CRANFIELD UNIVERSITY

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DEVELOPMENT OF AN OPEN-SOURCE VIRTUAL DESIGN FRAMEWORK FOR MEDICAL DEVICE DEVELOPMENT

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MRes THESIS

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Abstract

Economical and socio cultural changes have pressurised the health sector to become more sustainable. The sector is in need of a cultural change to bring more innovation in to new products and service developments. Diagnostic and therapeutic technologies need to be made available to the wider community. Allowing patients and clinicians to participate in the product development process has become essential; the current Intellectual Property model however does not accommodate this.

Open source is an approach to designing, developing and delivering knowledge through the commitment and contribution of geographically dispersed individuals. Patents and other legislative property enforcements are unnecessary, making OS products free. Other benefits include the involvement of users from a wide range of backgrounds brining to the platform a spectrum of skills and specialist knowledge.

The findings from this research detail the development of a generic concept creation model for medical device development in a virtual framework. Tools and techniques have been selected to ensure online collaborative development of the product is achieved through the concept creation stages. The biggest benefit of this research is the bridging between users and product developers in collaborative development. Limitations such as finding committed participants to continuously contribute through the concept creation process were also found.

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In the name of Allah, the Most Gracious, the Most Merciful.

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To my grandfather, friend and inspiration: Muhammad Sultan Ali Gondal.
An emerald in my eye, forever your affectionate memories remain.

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List of Acronyms

NHS	National Health services
SAS	School of Applied Sciences
OS	Open Source
C2C	Concept to Commercialisation
R&D	Research and Development
OEM	Original Equipment Manufacturer
SMEs	Small to Medium Enterprises
CAD	Computer Aided Design
VCC	Virtual Concept Creation

1. INTRODUCTION

This chapter aims to provide the user with an introductory opening of the research on which this study has been organised; it delineates the need for research, background, problem statement and the structure of the thesis.

1.1. Motivation

International economic and socio-cultural progressions have coerced healthcare providers to adopt a high level of sustainability. The end user demands are constantly increasing which need to be continuously solicited in the most adequate and cost effective way.

The effect through advancement of technological availabilities is twofold; firstly, patients are much more aware of opportunities, hence an increase in the levels of services and expectations. Secondly, clinical and administrative procedures have become more complicated, which need to be fully understood prior to execution.

Healthcare professionals' i.e. general practitioners, clinicians, doctors, surgeons etc. are becoming *'technology specialist'* through constant interactions with technology. By capturing their technical suggestions, specialist knowledge and technological interpretations will provide an insightful justification which can be useful in the development of medical applications.

1.1.1. Need for an Innovative Culture

The current culture within the medical sector appears somewhat out-dated, the need for a cultural change is apparent. By inhabiting a culture of innovation will encourage the germination of novel products and services which are developed around the user to suit the purpose in the most sufficient, cohesive and effective way.

Innovative led medical products development needs to be made affordable to third world and developing countries across the globe. Currently, diagnostic and therapeutic applications are only available to medical institutions that have sufficient funds to maintain the equipment. Such applications now need to be made available to the wider community.

1.1.2. Current Model

Comparably the model for developing medical applications is like most commercial products, which relies greatly on the generation and confinement of Intellectual Property Rights (IPR).

⇒ Universities are able to gain grants and funds available from research councils.
⇒ Large OEMs utilise R&D budget(s) to fund which are then deduced from the profits as overheads.
⇒ Most SMEs need to evoke sufficient funds in order to participate in this model.

1.1.3. Limitations of the IPR Model

The model as described in the previous section is but confined; it restricts complete association and involvement of stakeholders' i.e. medical professionals, SMEs and patients. SMEs are unable to part take in the model, innovative and vibrant ideas that carry the potential to be commercialised are unfortunately not communicated to the market due to insufficient funds for IPR. The involvement of patients influence in the development of medical applications, which may be considered as a dominating factor is non existent.

1.2. Open Source: Open Opportunity

Medical innovation based on open source principles possesses the potential to design and develop sustainable applications through collaborative involvement of individuals. The current model will be replaced with a framework which demonstrates transparency to aid in the evolution of designs based on contributions and reviews from peers.

A brief explanation in to the open source initiative and its cultural precepts has been discussed, providing sufficient background information to establish the foundations of this research.

1.2.1. Open Source Phenomena

Stallman, the ancestor of the free software foundation proposed a revolutionary concept in 1984 which gained established in 1998 (Fei-Rong et al., 2005). The concept took the name of Open Source, the development and growth of the initiative has been boosting ever since.

1.2.2. Openness

The term 'openness' is usually connected to open source communities; LaPorte (1996) defines it as being able "to look under the hood." Having the freedom to use,

distribute, and manipulate knowledge. Himanen (2001) explains openness as the freedom amongst the developers in sharing ideas and concepts with one another. Wendel de Joode and Bruijne (2006) complete the explanation by explicating openness as a building without any artificial fences which are open for insiders and outsiders to look in an out without restrictions.

Gacek and Arief (2004) in their article 'the many meanings of open source list two common characteristics found in open source communities:

1. Users must confirm to the 'Open Source Definition':
   1.1. Availability of the source code
   1.2. Distribution of the software freely
   1.3. Modification can be made to derived artefacts
   1.4. "No discrimination"
2. Developers are always users

1.2.3. Open Success

The notion of OS in principle is with the software industry. It is an alternative and more dynamic approach to proprietary software offered by vendors. Richard Stallman explains that there is a great deal of harm being caused to the society through the use of proprietary software. By allowing users to alternately adopt OS software would provide them with immeasurable benefits. The interest of OS software has been seen amongst the leading corporate after the success stories of Linux, Mozila and Wikipedia (Gilbert and Karahalios, 2009).

1.2.4. Open Source Establishment

Open source possess phenomenal innovation abilities which has had a great impact on industrial evolution, in the cyber world. Feller et al. (2005) outlines that with the 'circulation' of ideas that are not bound by any restrictions within in the 'bazaar' like environment, breed innovation. Wang and Chen (2005) believe open source as a new organisation that has established it's self firmly and will provide innovation in view of knowledge management. Additionally, Weber (2004) see a general view and hold the perspective that open source phenomenon is a driver for innovation for making knowledge publicly available.

1.2.5. Ten Key Factors

Xu and Wan (2008) have summarised ten key factors that are commonly associated with open source project developments.

- *Self-organising:* OS teams are self-organised and welcome individuals, there are no official contracts signed.

- *Code sharing:* sharing artefacts and codes is the key driver in OS projects.
- *Dissemination and Adaptation:* regular discussions are performed to reflect the progress and propose ways to be more productive.
- *Usability:* correct concepts, methodologies and common approaches are adopted.
- *Talent:* there are no restrictions on the number of participants, the age group or background.
- *Interaction:* the community release and respond regularly to identify predicaments.
- *Collaboration:* emphasis is made on team work and resource collaboration.
- *Happiness:* individuals usually share common interests on the project.
- *Democracy:* Power relations are unpractical, aggregation and compromise work.
- *Sustainability:* there are no restrictions on joining or leaving the projects.

1.2.6. Reliability

The question of reliability has been raised amongst the community, however the quality of artefacts produced within the OS communities are high in quality than that of proprietary software. Wendel de Joode and Bruijne (2006) record Apache having 31 defects in a line of 58,944 codes, which results in a defect density of 0.53 per 1,000 lines, and the average defect density of 0.51.

The transparent flow of information in open source communities allows participants to perform a smooth motion of information transfer which contributes to the production of reliability of artefacts.

1.2.7. Overview

The success via popularity and quality of outputs of the open source phenomena has been highlighted. Technical assurance suggests the initiative has been established and is being accepted globally at non-commercial and commercial levels.

The main focus of the open source community is in the development of software applications, it is hoped through this research a way to adopt the OS primitives in the development of life saving applications is achieved.

Concurrent and collaborative product development strategies are employed by high stream corporate. To inherit and employ such requires a great deal of financial supporting. Providing a web-based framework for sustainable product development using open source philosophies should eliminate the financial constraints but also involve whoever, whenever, wherever with whatever.

1.3. Aim

The aim of the research is to identify the potentials of using open source initiatives with a valid OS license to create medical concepts. This will be accomplished by developing a web-based, virtual framework that contains all the necessary tools, techniques and technologies to allow geographically disperse individuals to create concepts.

1.4. Thesis Structure

The thesis is a compilation of eight sequential chapters, each with a specific purpose which addresses the developmental aspects, providing details of particular tasks that constitute the research of the thesis (see figure 1.1)

- ⇒ Chapter One: initiates by providing the reader with preliminary information on the subject background; details of the problem, motivation and the structure of the thesis.
- ⇒ Chapter Two: an in-depth and extensive literature review is provided followed by comparative studies in the following areas: *Open source in the medical sector, examples of products developed by means of OS and products developed via web collaboration.* Furthermore a supplementary explanation in to the product development lifecycle is provided followed by the development of virtual concept creation process for the medical sector.
- ⇒ Chapter Three: details of the research aims, objectives, in-scope, out of scope and methodology adopted have been explained.
- ⇒ Chapter Four: provides a detailed explanation in to intellectual property and how one may protect the ownership of concepts within the open source paradigm. An applicable license is proposed followed by the creation of terms and conditions which the users must obey.
- ⇒ Chapter Five: delineates the development of the concept creation virtual framework, a detailed script is provided using use case and activity diagrams
- ⇒ Chapter Six: details of the user trial (implementation), for developing a medical product in the virtual environment is recorded
- ⇒ Chapter Seven: results of the user trial are discoursed which are subsequent of participant's response from the semi structures questionnaire that was developed.
- ⇒ Chapter Eight: the final chapter ceases with a detailed conclusion. Strengths and weaknesses of the methodology, discussion of the results and possible methods to adapt the process in to another sector are highlighted.

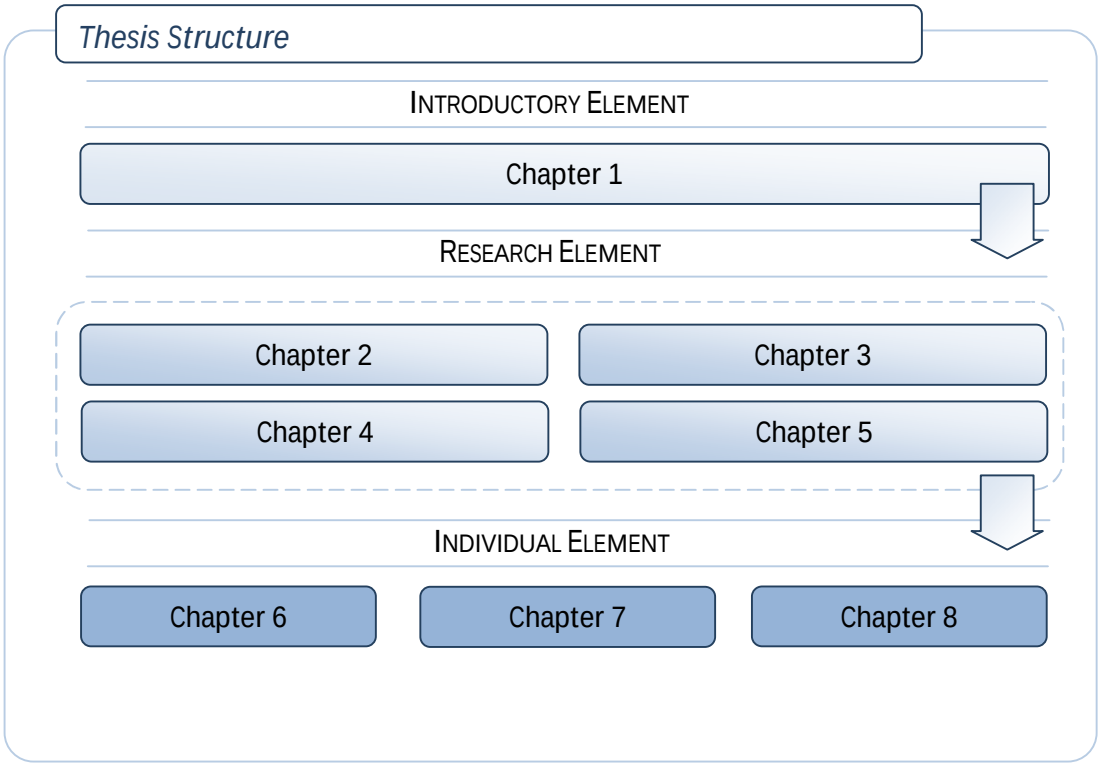


Figure 1-1: Thesis structure

1.5. Summary

The introductory chapter has the rendered explanations for the reader with reference to the nature of the research; key motivational factors, background information and problem(s) that are to be addressed have been exclaimed. To further enhance and support the research an extensive literature review has been recorded in the coming chapter, focusing on key topics such as: products developed using open source initiatives, examples of web-based collaborative designs, techniques used for virtual design collaboration and virtual product development.

2. LITERATURE REVIEW

2.1. Introduction

The following literature review has been conducted to assist in gaining a thorough understanding of the subject through an in-depth analysis of published literature. The main area of investigation is to see the impact of OS within the medical sector and how online collaborative tools and techniques can be used for concept creation of medical applications.

The review consists of five major segments which include:

- ⇒ Initiate with OS definitions, followed by analysis of how it's impacted the medical sector.
- ⇒ Comparative study of products developed using OS initiatives.
- ⇒ Comparative analysis of products developed using web-based collaborative design.
- ⇒ Open source for product design on the web
- ⇒ Concept creation in New Product Development (NOD)

After all five areas have been discussed a gap analysis will be conducted which identifies the possible areas of conducting research.

2.2. Open Source

A brief introduction in to open source has been provided in the previous chapter, this section will open with defining OS followed by assessing the involvement of OS in the health sector.

2.3. Open Source Definition

The open source community is built on the grounds of the OSI (Open Source Initiative) which provides a breakdown of the regulations under the title of OSP (Open Source Definition); ten regulatory statements have been listed (see Open Source Initiative, 2009).

Free distribution

The artefact is not to be bound by a license which restricts its distribution as a 'component of an aggregate,' no royalty or other type of fee should be accepted for sale.

Source code
The program must supply the source code with the compiled form of the artefact, if it's not distributed it must be 'well-publicised' which allow the recipient to gain access to it. The source code be in a modifiable form, deliberately obscuring the code is not permissible.

Derived works
The artefact should allow modifications and must permit distribution under the same license terms and conditions.

Integrity of author's source code
As a new release of products is made available and patch files are distributed, they must be designed to be adaptable. The latest build should permit distribution from the modified source code.

No discrimination against groups or persons
Discrimination of any type; person or group is not acceptable.

No discrimination against field of endeavour
The artefact is not to be restricted to a specific field of endeavour; anyone is able to make use of the product.

Distribution of license
The license is for all whom the artefact is redistributed to should not require an exceptional license from a third party.

License must not restrict other software
The singular license of the artefact must not enforce restrictions on other artefacts distributed with the package.

License must not be product specific
The rights of a product are not dependant on distribution, however when it's redistributed the third parties will possess the same level of rights.

License must be technology-neutral
A prediction or planning of a license cannot be made on the basis of technology or graphical interface of the artefact.

It can be seen that the OS initiative provides simple yet concise statements which build the foundations of the OS paradigm. The laws can be easily followed providing

2.4. Sectors

Open source is being considered as the first replacement option, its continuously being introduced to new sectors. The adoption rates are increasing, research indicates that its influential leads have given birth to a new dimensions of data exchange. Details of three sectors and there intent to adoption has been explained.

2.4.1. Academic Sector

The popularity of open source initiatives has bridged the gap between industry and academia. According to Shockey and Cabrera (2005), SNAP (Services Network Application Platform) has been developed as a collaborative platform for companies, governments and academia. It exemplifies a finishing school, allowing mature students to collaborate with researchers to instigate skills and technical knowledge to address real problems. Furthermore Benjamin Alfonsi (2005) highlights a valid point made by the British Educational Communication and Technology Association that state schools have as much as 50 percent cost benefits by replacing proprietary software with open source products.

2.4.2. Government Sector

Recent studies indicate that the government is very keen on adopting open source artefacts as explained by Hollmann and Hangjung (2008). An OS public administrative tool for Europe is under development. OSOR.EU[1] would serve as a repository system to aid in the reuse of solutions as faced by other countries. In addition to this Hollmann and Hangjung (2008) have recorded over 20 specific OS government projects.

2.4.3. Health Sector

Success stories of open source projects within the health sector have started to appear. Till now the health sector openly claim that they have never made IT as its leading priority and therefore is not up to speeds to it (Dinevski et al., 2007).

The health sector has been very quick in adopting OS applications partially due to the benefits available. A case study conducted on Beaumont hospital provides a list of IT related cost savings that were gained by adopting OS applications (see Fitzgerald and Kenny, 2003). Other benefits include regional collaboration within the health sector which will allow a successive exchange of information.

Examples of OS projects within the sector include World Vista, Prima Care, Open and EMed (Dinevski et al., 2007). According to Fioravanati et al. (1997) the EuroPACS society is developing an open system to store, maintain exchange and recall health records of all European citizens.

[1] Open Source Observatory and Repository for Public Administration in Europe

2.5. Open Source Application in the Health Sector

Continuing the investigation with the effects of open source on the medical sector it became apparent that applications had been already being developed and were currently in use. An analysis of five applications in the respective areas of communication and 3D visual representation has been discussed.

2.5.1. Communication Applications

	Project	Feature(s)
1	BioMail (Mozzherin.D, 2001)	*provides live update of diseases and other useful information*
Discussion: This is a very useful feature to have in the OSMI as it provides up to date information regarding diseases and other latest information. The OSMI should be the all-one-stop for researchers and practitioners and individuals interested in the medical sector, therefore having this application would be ideal.		
2	EpiSPIDER (EpiSPIDER, 2009)	*Historical timeline and record of diseases*
Discussion: A timeline is presented with details of announcements made on a particular. It allows users to back date and visually see these outbreaks. This fanciful technology could be adapted in the OMSI with the aims to provide participants the ability to keep up a track of the advancements made on the projects.		
3	RODS (Rods Laboratory, 2009)	*A visual representation of the globe with real time display*
Discussion: This is a fantastic feature which could be adapted to: *visually show global intervention of the participants.* In practise, when participants register on to a project, they will record their location[2]; this will be displayed on the screen to allow every one to see who is participating and from which country. This would be a novel and classy feature on OS projects, allowing a visual representation of the location of the participants.		

Table 2-1: Communication applications

2.5.2. 3D Visual Representation

	Project	Feature(s)
1	3D Slicer (3D Slicer, 2009)	3D visualisation of data
Discussion: Following a thorough analysis of the tool it appeared the visualisation tool was explicit to the area of research. Therefore this feature could not be used; an alternative method of standard graphical visual representation of CAD models i.e. VRML, IGES etc would need to be considered.		
2	Amide (Amide, 2009)	Analysing and registering models
Discussion: Initially the concept was intended to be used for analysing and register CAD models however the following complications arise: (1) the software is specific to the analysis and registering to medical data. (2) In the OSMI, every project will differ in terms of analysis required on the CAD model. The common analysis to be performed could include: FEA drop test, injection moulding simulation etc therefore the nature of the product will determine		

[2] Country and city *(address is not needed)*

the analysis required on it, and assigning one tool to address would be incompatible.		
3	ITK-SNAP (SNAP, 2009)	Interactive
Discussion: Interactivity with the model is important to allow users to grasp the complete perspective of the model. However this application is singular use and doesn't allow collaborative interaction, which is required in the OSMI environment.		

Table 2-2: 3D visual representation applications

2.6. Overview

The health sector has been looked in to; projects and applications have been reviewed. The e of web-based tools to develop *applications* using open source is currently in service. The applications in developed for the health sector cover a wide spectrum, some potentially having the capability to save lives, such a 3D Slicer and Amide.

As it appears, open source has been considered and utilised in many ways however all the end products are in the form of software applications. OS has been used in the creation of the software, no other contributions such as the development of products has been identified.

This literature review will lead the way towards the second part which will investigate the use of open source in the development applications other than software such as physical objects.

2.7. Comparative Study

The purpose of this study is to identify literature which discusses the creation of physical products using open source. Five examples are put forth with brief descriptions of the project with reference to the field of study and the country in which it was conducted.

This study will aim to identify the current progressions in the different sections and aim to build up on the current understandings of the technological developments via open-source initiatives. Not just as proposed initiative's but rather as physical products that have a specific demand or objective which has to be fulfilled.

	Title		Paper Reference:
[1]	An Open Source Based General Framework for Virtual Surgery Simulation		Chun and Wang (2008)
Discipline:	Health Sector	Sector:	Academia, China
Description			
Technological developments have introduced a new dimension in to surgery; VSS (Virtual Surgery Simulation) is being considered as a possibility for trainings and planning. A VSS framework has being developed though an elementary version is discussed.			
[2]	An open source IEC-61850 Toolkit for utility automation		Klein (2008)
Discipline:	Energy	Sector:	US DHS and US DE[3]
Description			
OSECS (Open Secure Energy Control Systems) has developed a 'toolkit' for secure electric power transmission systems. They have referred to the OS community to aid in the acceleration of the toolkit implementation			
[3]	An Open Source Parametric Propeller Design Tool		D'Epagnier et al. (2007)
Discipline:	Oceanographic	Sector:	Academia, USA
Description			
A user friendly computational propeller application has been designed using open source. The tool is flexible; it can be used by amateur engineers as well as well experienced engineers for the creation of designs. The tool has been validated with the US Navy's code; the tool is fully functional and is made available in a part of a suite of OS tools for rapid design for propeller designs.			
[4]	Development of an audio player as system-on-a-chip using an open source platform		Kiatisevi et al. (2007)
Discipline:	Acoustics	Sector:	Academia, Germany
Description			
OS tools have been used in the development of a System-on-a-Chip (SoC) audio player. An operating system has been considered, and a decoding tool has been developed and evaluated.			
[5]	Closed and open source neuro-image analysis tools and libraries at UNC		Styner et al. (2006)
Discipline:	Medical/ Psychiatry	Sector:	Academia, USA
Description			
An open source initiative to develop an application for Neuro-image-analysis has been developed. A repository has been developed and segregated in to two sections, one open source and one closed source. With this approach the participating parties claimed to have identified positive results.			

Table 2-3: Literature for comparative study

[3] United States Department of Homeland Security and the United States Department of Energy

2.7.1. Criterion for Assessment

A set of generic criterions have been produced which will be used to collectively assess the five papers. It is hoped by doing this an establishment of key findings of techniques and methodologies used to produce the products will be achieved.

1 What was the intention of the project?
The intent will provide a background understanding of technologies being used.
2 Why was Open source considered?
This question aims to outline the reason for selection.
3 What tools were used?
Numerous tools and applications are available in the open source community, this aims to outline which were considered.
4 Did the project gain popularity?
Majority of open source projects fail which is due to lack of interest of participants. The goal is to find out if the project gained popularity
5 How was the overall experience?
This criterion aims to capture the personal experience of the team.
6 Was a final product developed?
Developing a finalised product suggests the development beyond detailed design.
7 Was the product evaluated
Product evaluation is conducted during the finalisation of any project; this will test the maturity of the product.
8 Which OS license was considered?
This will define if the committee considered publishing the project though careful selection of a license to make it publicly available.
9 Will OS be considered for further development?
The success of a project either through achieving the target or gaining experience, knowledge, skills etc. usually determines whether a developer will consider using the same strategy again

Projects	Case Study	Paper Reference
Project 1	A Open Source Based General Framework for Virtual Surgery Simulation	Bao and Wang (2008)
Project 2	An open source IEC-61850 Toolkit for utility automation and wind power applications	Klein (2008)
Project 3	An Open Source Parametric Propeller Design Tool	D'Epagnier et al. (2007)
Project 4	Development of an audio player as system-on-a-chip using an open source platform	Kiatisevi et al. (2005)
Project 5	Closed and open source neuro-image analysis tools and libraries at UNC	Styner et al. (2006)

Table 2-4: Organisation of case studies for assessment

2.7.2. Comparative Study: OS Product Creation

1 Criterion 1: What was the intention of the project?	
Project 1	⇒ Performing surgery is highly critical which postulates a great deal of precision, planning and experience. ⇒ Live human organs are not obtainable for 'dissection' though the use of animals is imprecise and is surrounded by ethical issues (Bao and Wang, 2008).
Project 2	⇒ Klien (2008) states the intent "was to address electricity utilities and their equipment providers to migrate to the more easily secured IEC 61850 families of utility automation standards."
Project 3	⇒ Developing a user friendly application that would aid the design of propeller/turbine blades.
Project 4	⇒ Developing a system-on-chip audio player which uses limiting computing resources and lower power consumption (Kiatisevi et al., 2005).
Project 5	⇒ Open source is widely used in the medical sector for image analysis; the intent was to develop a repository of all the in-house applications and tools.
Analysis:	The variation of the projects is wide, two for which are associated with the health sector. Surprisingly all these projects performed were a part of well-established and institutionalised organisations.

Table 2-5: Comparative study criterion 1

2 Why was Open source considered?	
Project 1	⇒ Simulated virtual surgeries are being used in medical society and simulations of human organs i.e. liver, heart, eyes etc have been performed. ⇒ Open source will be used to "construct and integrate and applied real-time application framework" (see Bao and Wang, 2008).
Project 2	⇒ Open source would be used to develop the toolkit for developing the system.
Project 3	⇒ The parametric modelling application is to be designed using OS tools, it is to be utilised by designers and engineers with different levels of experience.
Project 4	⇒ Open source software would be used to reduce the development and licensing cost of the finalised product.
Project 5	⇒ The field of collaboration between libraries was open, and the need to develop a system which would allow the compilation of applications in to a single system would be made possible.
Analysis:	Paper 1, 2 are benefiting for the public, it seems like OS is usually based on interest and wishes to use OS tools to get the job done. Other papers indicate cost reduction factors and making knowledge widely available.

Table 2-6: Comparative study criterion 2

3 What tools were used?	
Project 1	⇒ The framework was developed using: "C++[4], STL[5], Boost, OpenGL, Python, PyQt and XML" (Bao and Wang, 2008)
Project 2	⇒ The following OS tools have been considered: OS client stack, MMS interface and message, messaging client, Python, C++, MySql, Octave[6] and web services. ⇒ The toolkit was developed on Linux (with enhanced security features) which were developed by the National Security Agency of the U.S. Department of Defence and NSA.
Project 3	⇒ Specific details of the OS applications/tools used are not mentioned, D'Epagnier et al. (2007) mentions "this propeller design software is part of a suite of open source tools."
Project 4	⇒ "OGG-Vorbis reference library, RTEMS operating system, LEON Soc platform and GNU/Linux workstation" were all used in the development of the application (see Kiatisevi et al., 2005)
Project 5	⇒ Standard tools such as CVS, Doxygen and CMake were considered.
Analysis:	Interestingly the most common tools listed above are related to software engineering. Common operating systems have been chosen for the creation of the artefacts.

Table 2-7: Comparative study criterion 3

4 Did the project gain popularity?	
Project 1	⇒ The project was an academic approach in to solving the predicament, OS libraries and tools were used however the project wasn't exposed to the Open community.
Project 2	⇒ It appears the project wasn't opened for public participation due to the nature of the project.
Project 3	⇒ The project is technical and subject specific, by assessing the case studies discussed in the paper it is clear individuals from out the project team were involved who evaluated the tool.
Project 4	⇒ The application is licensed under the LGPL license.
Project 5	⇒ Internally the project gained popularity, however there is no mention of an outdoor popularity (in the common public sector).
Analysis:	Surprisingly none of the projects were made publicly available, even though the use of OS revolves around communicable and public input.

Table 2-8: Comparative study criterion 4

[4] Programming language
[5] 3D CAD geometrical format
[6] Advanced power system applications for power flow

5 How was the overall experience?	
Project 1	⇒ From an analysis of the paper it became clear that the tool was successfully developed, adoption of file formats was achieved. ⇒ The author has presented Images which demonstrate the tool in function.
Project 2	⇒ The author provides a lengthy description on the lessons learnt, and through examining the comments it is clear that the user has gained a thorough understanding of OS. ⇒ The author hasn't commented negatively on any of the OS principles or working practices.
Project 3	⇒ The author expresses the overall experience as being successful, all the objectives were met and the output was exceptional D'Epagnier et al. (2007).
Project 4	⇒ The success of the project has been recorded and explained and intents to undertake further development are also visible.
Project 5	⇒ According to the author the final solutions fits the purpose and the development time was shorted with an enhanced interaction team.
Analysis:	All of the projects were successfully completed and the overall experience of the team was recorded to be positive.

Table 2-9: Comparative study criterion 5

6 Was a final product developed?	
Project 1	⇒ The tool has been developed as an elementary version which is working though requires further development.
Project 2	⇒ A final working tool was developed and is also being developed further and maintained.
Project 3	⇒ A final working prototype has been developed.
Project 4	⇒ The paper suggests an application was successfully developed.
Project 5	⇒ A final product was developed and supporting material i.e. training, on-going development etc. has also been developed.
Analysis:	The proposed targets set in the initial stages of the research were met by all the authors, a final product was develop din all five cases.

Table 2-10: Comparative study criterion 6

7 Was the product evaluated?	
Project 1	⇒ Bao and Wang (2008) state that "we'll enhance elementary function by means of testing and studying newer algorithms to make the system more flexible."
Project 2	⇒ Specific details of product evaluation have not been given, possibly due to the nature of the product.
Project 3	⇒ The application was tested with three cases to demonstrate its capabilities and all cases were successful. ⇒ The application was extended further, it provides graphical representations but also the ability to print a 3D prototype.
Project 4	⇒ Technical records of the tests performed have been listed.
Project 5	⇒ It is clear that the libraries were tested for functionality aspects.
Analysis:	Product testing and validation was performed for all the products developed and all the papers reported to have had positive output of results.

Table 2-11: Comparative study criterion 7

8 Which OS license was considered?	
Project 1	N/A
Project 2	⇒ Dual License, Public and commercial
Project 3	⇒ The application developed was licensed under the GNU public license.
Project 4	N/A
Project 5	⇒ The Berkley style license was considered for the open part of the repository.
Analysis:	Three projects highlight the use of OS license adoption with one case of commercial extension. All three licenses are amongst the common types adopted by user.

Table 2-12: Comparative study criterion 8

9 Will OS be considered for further development?	
Project 1	⇒ The authors have expressed their interest to further develop the tool, which therefore suggests they will continue to consider using OS applications.
Project 2	⇒ The success of the project has been expressed by the author, and it is therefore most likely that OS will be considered further.
Project 3	⇒ D'Epagnier et al. (2007) "plan to add more advanced features to the design suite, and encourage others in the propeller design community to further develop the code to match their needs."
Project 4	⇒ "Lessons learned in this project could be applied to others in the future" suggests the developers will consider using OS again (see Kiatisevi et al., 2005).
Project 5	⇒ "We are highly motivated and committed to stay with it" (Styner et al., 2006)
Analysis:	The results of the current projects have convinced the researchers to continue using open source to either further develop the project or consider it for new projects.

Table 2-13: Comparative study criterion 9

2.8. Overview

Conducting this comparative review has provided sufficient justifications that the use of OS tools can be made to develop applications other than software. All the cases studied were from respective sectors which included the US Navy and the medical sector.

All the projects ceased with positive results, users reported the experience as being enriching and worthwhile (Styner et al., 2006). The success of developing fully functional prototypes has given the team's adequate confidence to continue using OS in the development of product.

It would be necessary to indicate that details of the projects progression were provided in all five cases however all five reviews contained weaknesses. The major weakness was that the method for product development especially concept creation was not covered. OS works very similar to collaborative product development, in principle; however the papers also failed to record such details.

This comparative review has been sufficient in reaching the understanding that OS can be and has been used in the development of applications other than software. However additional research is to be conducted which will focus on web-based collaboration in the development of products.

2.9. Collaborative Virtual Product Development

This section will now focus on aspects related to collaborative development within a virtual environment.

2.9.1. Virtual Design Tools

The emergence of VR (Virtual Reality) technologies has given designers the freedom to manipulate 3D solid models in a virtual environment using VR tools i.e. HMD, BOOM etc. (Stelzer et al., 2009). By incorporating VR in to the design process the model creation time is increased and the enhancement of design development experience is also ameliorated. According to Semeraro et al. (2009) VR tools in a collaborative environment provide users sufficient space to undertake a critical analysis of the design prior to its manufacture.

Blumel (2008) strongly argues that VR environments can be used throughout the product lifecycle up until the operational level. However Kock (2008) suggest the use of VR applications for e-collaboration and e-commerce, he bases this on the idea of Secondlife and Wold of Warcraft abilities to develop as a mass market.

VRDS (Virtual Reality Design Systems) are now widely being used for solid modelling which aims to provide designers the upper edge or the 'intelligent support' by which they are able develop models in an 'intuitive way.'

2.9.2. Virtual Realist Design System

Virtual Reality Design Systems (VRDS) provide functional 3D models which are simulated for an all-round experience, for instance compasses and protractors are available which a designer is able to gain hold of and use it as you would in the real world. Virtual Design Tools equip a designer to construct models 'intuitively' throughout the development stage which takes designing to another dimension (see Stelzer et al., 2009)

2.9.3. Virtual Product Development

Developing prototypes can be financially heavy; designers have always hoped to reduce this cost developing and evaluating designs in a 'synthetic' three dimensional (3D) environment. Virtual environments are being considered by industry, academia, government and researcher as a possibility to undertake the design and development of products (Bochenek and Ragusa, 1998).

The product development process has taken a managerial stance and encourages the use of multifunctional teams. It has now become a requisite for individuals to share valuable information and collaborate with one another to make decisions.

Through interaction and collaboration, information access and exchange is mad easy during the design phase(s), giving everyone involved the opportunity to influence the final design.

Many have provided an insight in to the design review process; some appear more formal than others. It is extremely important to understand the design review process will differ according to the sector and type of project being developed.

View 1: Pugh (1990) explains the design review process as an important segment of 'modern industrial practice.' By performing design reviews the team is able to collate various cognitions in to a pool which aids in the development of a balanced design activity.

View 2: Mitchell (1994) suggests by performing design reviews through information exchange, interaction and collective agreement an optimal design can be achieved.

View 3: Juran and Gryna (1993) define design review as a formally constructed process that is documented and follows a systematic examination of the design against its

requirements. Problems are identified and solutions are proposed and thoroughly analysed by the team before an agreement is made.

2.10. Overview

After discussing the key elements associated with virtual product development, the next section will focus on non-virtual aspect. The traditional method of collaboration has been looked at however with the influence of web-based systems.

2.11. Web-based Collaborative Design

Web-based collaboration methods have gained popularity since the last decade, presented is a comparative study of the projects that have considered using web-based elements for collaborative product development. Table 2.14 records the papers that have been reviewed followed by respective sector the study belongs to.

ID	Title	Sector	Paper Reference
CS 1	A framework for distributed Web-based micro system design	Systems Engineering	Saha and Chandrakasan (1997)
CS 2	A Framework for Web-Based Interactive Applications of High-Resolution 3D Medical Image Data	Medical	Danzhou et al. (2006)
CS 3	A Web-Based Product Modelling Tool – A Preliminary Development	Mechanical Engineering	Xu et al. (2003)
CS 4	Constructing the simulation examples for the courses of dynamics and fluid mechanics by X3D	Engineering	Tsai et al. (2004)
CS 5	Enabling The Web-based Intelligent Product Design	Design Engineering	Wei and Heiu-Jou (2006)

Table 2-14: Web-based comparative table

Comparative Study

The comparative study looks at the following section:-

- ⇒ Nature of the project: aims to identify what's the meaning of the project
- ⇒ Intentions for using the web-based technologies: this will capture the reason why the project team has decided to consider web-based technologies.
- ⇒ Success levels: this aims to understand whether the team was successful in creating the proposed product using the proposed technologies.

This review will provide an understanding of the success levels associated with web-based technologies. It will also provide an understanding of the technologies used and the benefits they have to offer.

Comparative Study: Web-based technologies		
Nature of project		
Project ID	CS 1	Microsystems are becoming highly complex, the 'system-on-a-chip' can contain up to a million of transistors. The development of these can only be achieved through distribution and a collaborative design framework, which would serve as platform for information flow (Polys et al., 2008).
	CS 2	The technological advancement of medical imaging devices has allowed practitioners to get high quality outputs; the 3D data can stress the storage system due to the large files (Danzhou et al., 2006)
	CS 3	R&D and manufacturers of globally-based enterprises need to be communication throughout the product lifecycle. Through collaboration the product life cycle time can be shortened hence ensuring competitiveness (Xu et al., 2003).
	CS 4	The influence of 3D virtual reality simulation goes unnoticed especially when it comes to problem-based learning. A model needs to be developed which provides distributed web services and can withhold the integrated 3D contents (Tsai et al., 2004).
	CS 5	Product design consists of procedures that are demand coordination, each designer playing a vital role. Many design tools used throughout the process from conceptualisation to advanced CAD modelling (Wei and Heiu-Jou, 2006). Currently there is no collaboration and communication between the data systems, an intelligent system should alloy the integration and collaboration of these tools in developing stronger communications to improve the overall productivity.

Table 2-15: Nature of project

Intention for using Web-based collaborative technologies		
	CS 1	The world wide web provides designers with the opportunity to access and distribute information; many platforms have been developed to allow this remote access directly through a browser. Providing designers with access to tools is necessary however by building a global community the number of tools and resource will also increase which will give more opportunities to the designers. Resources, tools and techniques could be utilised by the designers irrespective of their location, this would result in an effective exchange of information which would simplify the deign process.
	CS 2	High resolution 3D (three-dimensional) visual data is used within the medical sector which is acquired through many technologies which includes MRI (Magnetic Resonance Imaging), ultrasound etc. The size of these image files is very large which can range from hundreds of megabytes to several gigabytes. Due to this increased size of the files the storage systems encounters a great deal of stress. Exchanging the data becomes challenging and in some cases impossible. A web-based system would aid in the reduction of storage size and communal cost that occur when exchanging data.
	CS 3	The traditional product development cycle is very extensive and a fast moving and highly demanding marketplace requires shorter product life cycles. Collaborative design is a way by which efficient product development can be

		achieved. A web-based product development environment will allow internationalised dispersed teams to engage in activities to overcome problems quickly and speed up the product development process.
	CS 4	Dynamic Fluid mechanics is a course being taught at National Taiwan University. The course aims to enhance the learning experience by providing students an interactive environment which will enhance their learning.
	CS 5	Designers are required to use different software tools throughout the development cycle. To increase competitive advantage there is a need to consider digital product development techniques. By developing an intelligent framework which incorporates some of the applications used by designers would promote data sharing via Virtual collaboration making the process less resourceful and cost friendly.

Table 2-16: Intention for using web-based technologies

Success levels	
CS 1	The tool was successfully developed under the name of WebSpice and can be accessed on the internet on the following link: http://apsara.mit.edu/spice.html. Screenshots of the tool have been presented showing the overview of the interface and how one can navigate through the different modules. Minimal errors were detected during the testing phases which were resolved with minimum effort.
CS 2	The application was tested and the results were favourable, some of them have been listed: A 457 MB file was compressed to 150Mb while retaining a high percentage of the quality. 200 standard queries can take up to 0.81 seconds while the system achieved this in 0.34 second. 15 graduate students tested the system concurrently and it was observed that the communication was achieved without any interruptions. The students accessed the server constantly for 1 hour and viewed high resolution 3D images and the response received from the system was 0.8 seconds.
CS 3	The goal of this project was to develop a collaborative environment for designers who could benefit via internet. A web-based JAVA solid modeller for collaborative design was successfully developed. Though it is in preliminary stages there is a hope to develop it further using latest technologies. However the project in is self was a high measure of success.
CS 4	An interactive 3D web-based frame work was developed which provides students with the course information. The contents included "particle dynamics, conservation of momentum, rigid body motion, free and forced vibration and conservation of angular momentum" (see Tsai et al., 2004). The topics are then further arranged in to three categories of complexity, giving students the opportunity to explore the topics from elementary to high class level. Details of testing or implementing the system have not been listed however screenshots delineate the graphical interface.
CS 5	A framework has been developed which can produce a 'smart product model' by reducing inconsistencies between different CAD and CAE packages. The intelligent framework accommodates different multimedia libraries which allows designer to make use of them during design challenges. Information can be exchanged and integrated; designers can collaborate and conduct service transactions without any difficulty.

Table 2-17: Project success rates

2.12. Overview

Five case studies have been reviewed, the key findings suggest that regardless off the sector the project teams can come together and collaborate online to develop products. This is a more resourceful and sustainable approach to product redevelopment.

2.13. Open Source for Online Product Design

The utilisation of open source concepts in software and products has been identified; however this section goes beyond that by identifying open source websites which allow for 'online collaborative product design.' This investigation will firstly clarify the abilities of utilising open-source for multiple purposes; additionally give an insight in to how the developers developed the framework – which could support this project.

Thorough investigation of online initiative's for 'online collaborative product design – using open source principles' revealed only one website which offers this service. This suggests there is a great potential for a project like this, however the difficulties shouldn't be under estimated. However there is a widespread of discussion in forums which highlight the potentials of open source in product design. This section will initially detail the discussion discussions on the potential of open source product development via web and then will continue with an example of a website with examples of projects.

Philips Online Survey

During investigation it came to awareness that there was an interesting survey being held on the subject of Open Source Product Design. Philips, a well-established and recognised electronic company hosted an online survey. This being an open discussion, allowed users to register and part take in the discussion. Details of the survey and the discussion have been critical analysed and presented

Interestingly, the same question that was being investigated in to, was already been discussed amongst a wide audience[7]. The case presented was supported by two reasonable arguments; the participation levels appeared high. The comments made by the audience have been analysed and key points have been extracted.

[7] http://www.livesimplicity.net/insights/internet-tech/open-source-product-design

Figure 2-1: screen shot of Live Simplicity discussion

Extracting utile comments from the discussion

Through the discussion a great deal of thoughts and ideas were exchanged and transmitted, these have been captured and presented; an attempt has been made to further explain them to determine whether they are for or against open source product design.

Comments	*Explanation*	*Response*
OPD is a great idea and if executed correctly it could revolutionise the way in which products are designed.	The overall view of OPD is accepted on the basis of successful execution. To successfully create such a system would require a few years.	For
Is this another means to gain free development?	Participants must appreciate and understand the concept of open source and read the licence agreement of the service provider.	Against
Product development is a very costly aspect of production; the cost can be reduced by global contributions.	Companies invest a great deal of money and time in to the product development process. This method could be used to carry out parallel activities	For
Profiteering from individuals contributions will discourage involvement	Doing it solely for the sake of money implicitly destroys the purpose of open source product design	Against
Open source product design will welcome variation and innovation.	Worldwide contribution of ideas and suggestions will give birth to innovation hence offering high quality goods to the market for less.	For
Global ideation is forward thinking.	International production of goods can be achieved through global interaction of customers. OPD can be utilised as a tool to identify individual and cultural needs allowing manufacturers to trade to the global market.	For

Table 2-18: Philips survey comments

Survey Conclusion

The discussion concluded with some bold statements which somewhat reflect the responses made by the participants. Some aspects have been covered however the flexibility of open source concepts has been undermined. An attempt was made to identify and explain any unclear ideas held by the participants.

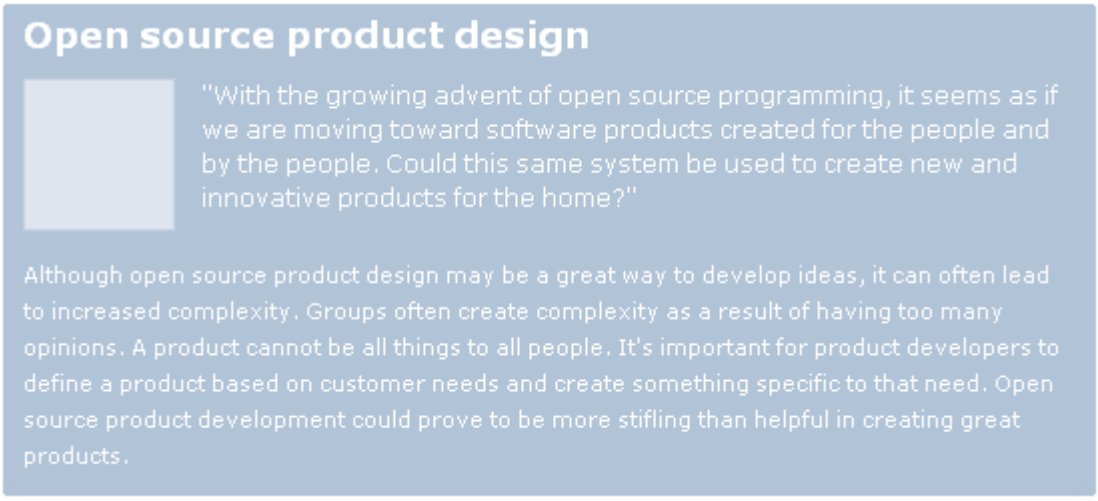


Figure 2-2: Screenshot of the conclusion

The results gained form this study are somewhat satisfying, an inner perspective of the general community has been captured allowing a clear understanding of the major concerns that may arise. The general comments have been positive however convincing the masses would mean to eliminate major concerns. One of the major concerns identified was related to the mechanisms of OPD.

It is absurd to believe one can enter a collaborative virtual environment and start designing products of their choice. This would result in a chaotic and stifled environment, lacking order and direction.

2.14. Open Access Polls

In addition to the review of the Philips discussion forum, this section will review open access polls and provide statistical information regarding open source for product design. In general, the success of open source product design lies within the community; levels of acceptance and rejection will be apparent, therefore the investigation is to inquire in to which option possess the likelihood. With this in mind a preliminary search was undertaken to see if a question of this nature had been polled. The search resulted in a positive response and an example of poll had been identified which directly focussed on this particular area.

Question asked

It was in the interest of this poll to capture and quantify peoples "willingness" in using/not using open source products.

Results

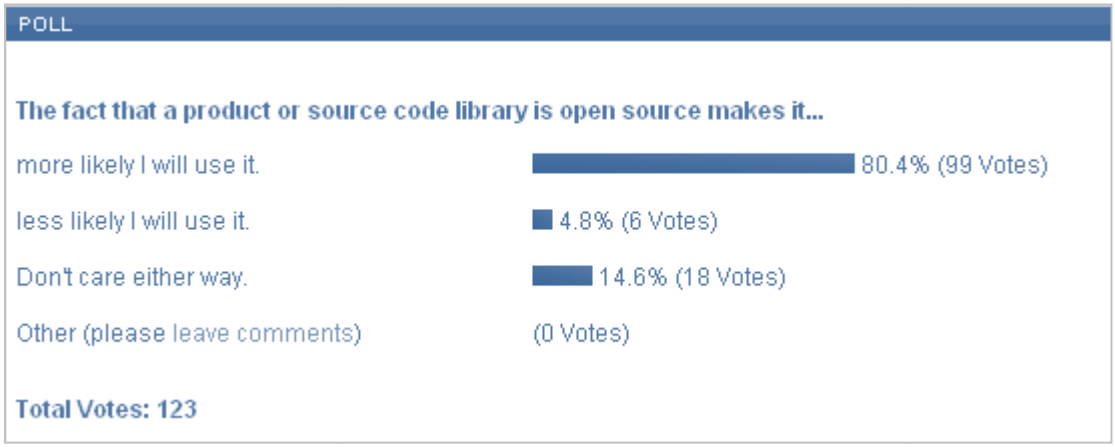


Figure 2-3: Screenshot of the results from the poll

- The results margin is wide, 80.4% have shown an interest and willingness in the use of open product designs. This is clearly demonstrates the popularity and keenness amongst people in using open source.
- There appears to be a group which don't show concern whether the product is open or closed. These individuals are not bothered with the history or the development of the product; they are solely interested in the product alone.
- Surprisingly a very small percentage of 4.8% expressed unwillingness towards open source products and openly expelled the thought of using them. However as popularity and acceptance grows towards open source products the minority will join the majority.
- The results exclaimed on the poll suggest a high percentage of the community shows willingness in adopting and utilizing open source products. Generally this is great, technically the reliability of the results is yet to be questioned.

2.15. Open Source Product Design Websites

A number of forums, polls and discussion points were used to gather information on existing open source- product design websites that were currently available or were under construction. The results of the investigation highlighted a single website that sought open source as an intuitive in the developments of its product; the proceeding section will provide a detailed insight in to this.

OPEN2: Online Product Design

OPEN2[8] is an online collaborative environment which is being used as a tool to allow individuals to part-take in the development of products. The site provides an overview of the mission statement and contact details. OPEN2 Clients and current projects are listed, viewers to do not have to register to view any of the projects.

OPEN2 claim to be open source, furthermore an organisation that promotes online design collaboration. The concept is very similar to crowd sourcing; however the site does not claim that. The framework has been captured with the intent to discover the underlining structure of the site, screen shots have been captured followed by descriptions.

Home Page

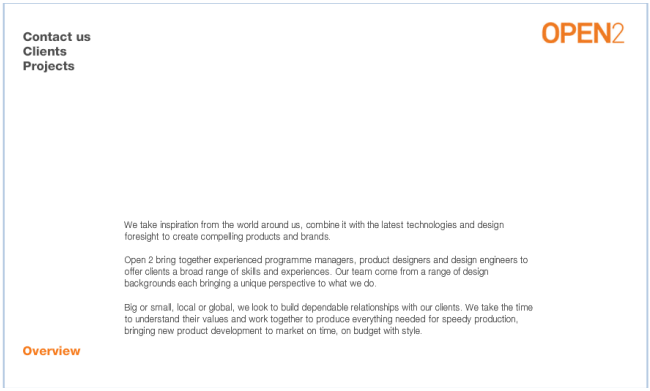


Figure 2-4: OPEN2 company overview

The homepage simply provides the users with an overview of the company mission and background, outlining the motive of 'developing products in style' for a speedy production through user participation.

Clients Page

Figure 2-5: OPEN2 Clients

[8] http://www.open2design.com/

Figure 2.5 captures the client's page which lists clients that are currently involved in OPEN2 projects. Users may click the clients' link to access the details of the projects otherwise click 'projects' from the navigation bar.

OPEN2 Projects: *YALE (locks)*

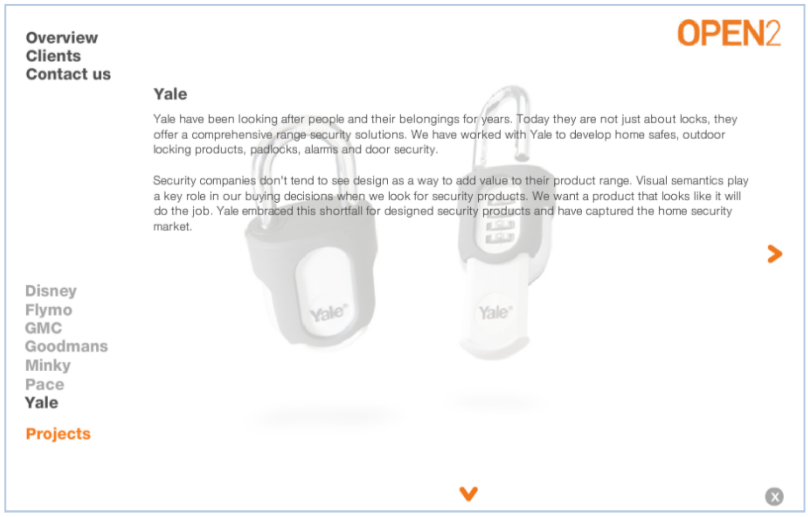


Figure 2-6: OPEN2 project description page

Concept 1

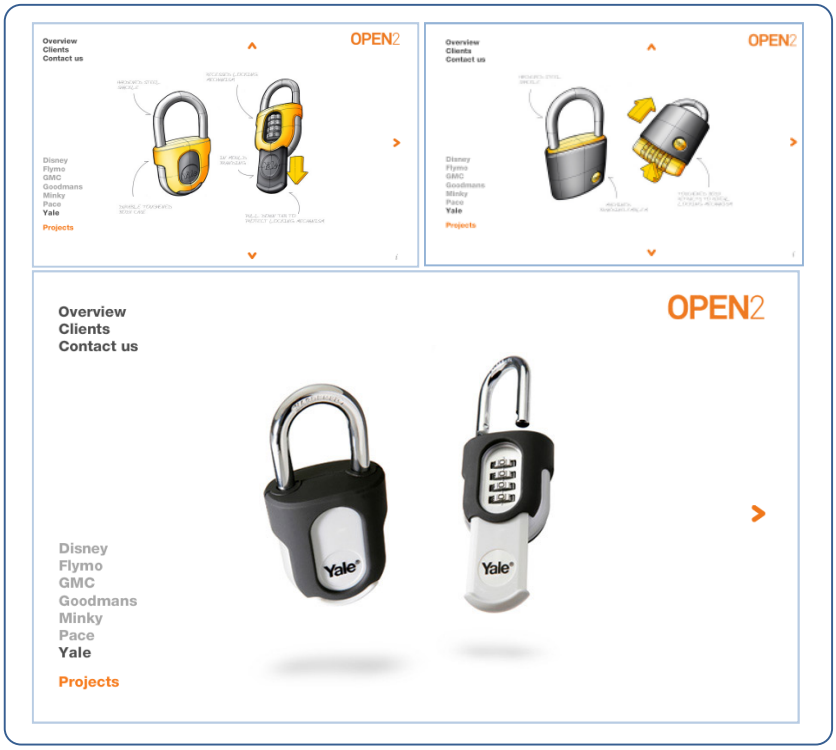


Figure 2-7: YALE concept 1

Concept 2

Figure 2-8: YALE Concept 2, screen shot of the CAD model and digital render

Navigation

The interactive screen has been placed as a centre piece on the site; in relation to the other contents of the site this appears to be the main focus. After selecting a project the concepts are made visible for the viewers to see.

^	By selecting up users are able to see a photo realistic CAD model of the concept
>	By selecting right the users are exposed to other concepts (ascending order)
v	By selecting below the a digital render/sketch is shown of the concept
<	By selecting left the user returns to the previous concept

Table 2-19: Navigation buttons

YALE project overview

The Yale project was selected, the first image to appear on the interactive screen was a description of the project (figure 2.6). By selecting the right navigation button the concepts uploaded by participants appeared. Once a concept appears the user is able to select the bottom button to navigate from a digital render to a CAD model.

Figure 2.8 displays the second concept of the YALE project, both the CAD model and the digital sketch with annotations. The theme, structure, proportion of the image etc. is very similar to the previous concept. As it appears all the concepts displayed carry a standardised theme which provides a coherent and consistent overlook of the project.

Limitations

After analysing the projects on the site it became apparent that the entire project carried a consistent theme, which portrayed the concepts in an elegant way. However there were limitations with the projects which include: [1] the images were static, [2] the users didn't have access to the data files (CAD files), [3] images are pixel and not vector (see figure 2.9), when zooming in the text becomes blurred and [4] though the interface is flash users are unable to interact with the CAD model.

Figure 2-9: Content zoom-in

OPEN2 Project Framework

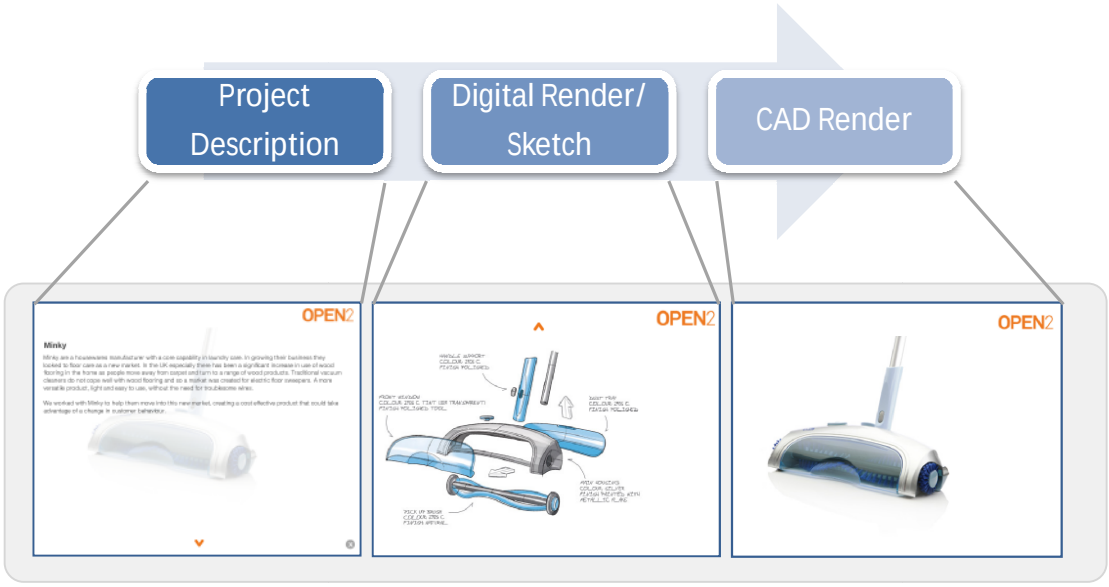


Figure 2-10: OPEN2 project navigation

From analysing the website it is made to notice that the background framework for all the projects is based on three parts: [1] project description, [2] Digital render/ sketch and [3] CAD render.

1. *Project Description:* Details of the company and its projects are provided, this serves as an initial open specification of the project which allows users to use open guidelines to develop concepts.
2. *Digital renders/sketch:* Annotated sketches and digital renders are presented to indicate key features of the concept in exploded view.
3. *CAD Render:* A photorealistic image of the concept is presented for visual purposes.

Results

OPEN2 is a small captivated website which provides users an experience to participate in projects. Clients upload details of a project and provide initial concepts (digital renders and CAD models) which are able for visualisation.

The structure of the site is very simple, one can navigating throughout the site without much difficulty. The appearance and the contents of the site are professional looking and aesthetically appealing.

There is however very limited amount of information about the OPENT2 initiative, there isn't a section on FAQ and user support which is very off putting. The OPEN2 foundation is promoting design collaboration however the online environment doesn't have necessary tools and functions available to allow this, which must mean the website is being used as a mirror to host projects.

The technologies used in OPEN2 are rather out-dated and limited in terms of functionality. The interactive screen is based on Flash, all the images provided for each of the projects but appear as organised slide shows. All the images are static, the user is unable to pan, zoom or rotate the CAD models to get an additional view of the concept from another perspective.

The quality of the images and CAD models provided is high but access to the data files in not provided. In a collaborative environment the user should be able gain access to the original data for viewing and editing.

The site has been recognised for its elegant and modernistic appearance and framework however it lacks much to provide a platform for a collaborative environment. More detailed descriptions are required; each image requires needs to be detailed accordingly. Advisably, vector graphics should be replaced by the currently used pixel files to ensure quality of the image is maintained.

To develop the site further it is recommended that more details of the initiative, projects and concepts is to be provided. Original files are to be made available for download. User requirements for the project are not clearly defined; therefore an extension to each project should be made which is solely dedicated to requirements.

2D drawings should be used to support the CAD model; details of the software packages used to generate the models should be listed to inform users. VRML, IGES, STEP or other universally accepted CAD model formats should be made available for download.

2.16. Role of concept creation in New Product Development (NPD)

The focus of the last section of the literature review is to describe new product development and the role of concept creation in it. Moreover, identify a medical product development process and comprise a generic product development model, in a virtual environment. Graphical illustrations and explanations of key activities have been accounted.

New Product Development

New Product development is the process of introducing new products to the consumer by a business. Typically the cycle fits a basic four stage process which includes: concept creation, design and development, validation and in-service product support (see Wheelwright and Clark, 1992).

⇒ *Preliminary concept creation:* is the process of identifying customer needs and the generation of concepts with an economically justified specification (Wheelwright and Clark, 1992).
⇒ *Design and development:* deals with the generation of schemes of the product with specific functional specifications of the major processes.
⇒ *Validation:* is the analysis and affirmation of strategies to reduce risks and increase the benefits of the expected product. This process has the potential to increase the quality of the product (Cooper, 1994).
⇒ *In-service product support:* after a product has been launched in to the market, manufacturing is imposed and the service is monitored.

Comparatively, Kurowski & Knopf present a generic frame work of a product development lifecycle, providing an emphasis on the concept creation.

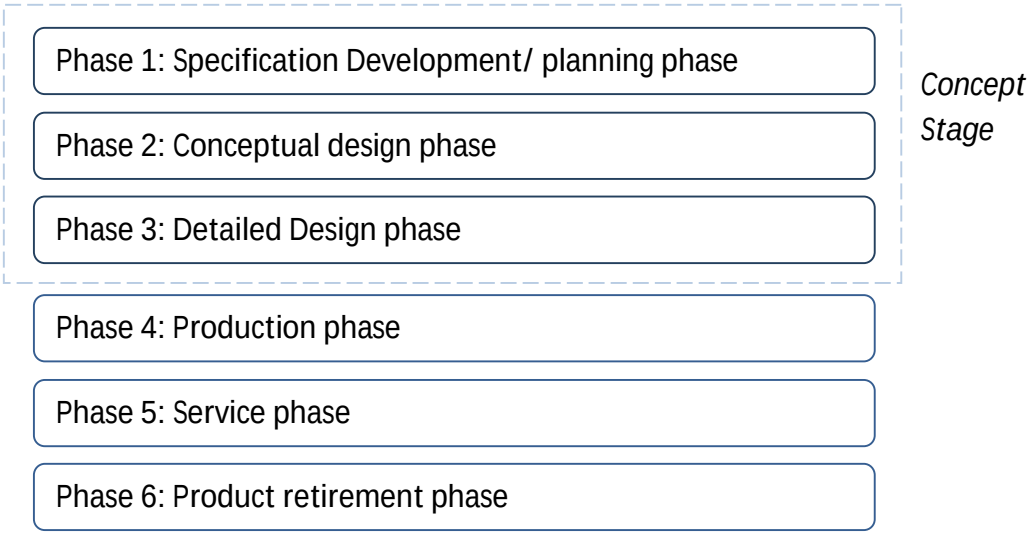


Figure 2-11: generic product development lifecycle (Kurowski & Knopf)

Though both generic processes put forth a valued explanation of the product development process, one must appreciate the influence and importance of the design phase. Design refers to all the activities and process involved in the creation and aesthetics of the product. Decisions are made on its mechanical and structural compilations; fundamental functional components are also identified.

The term development is given to a collection of process that deals with identifying market opportunities and finding solutions that are most appealing. The process follows through the creation and testing of prototypes for refinement until its ready for production.

Medical product development lifecycle

The generic process for product developments is not sufficient for medical applications due to the nature of the products.

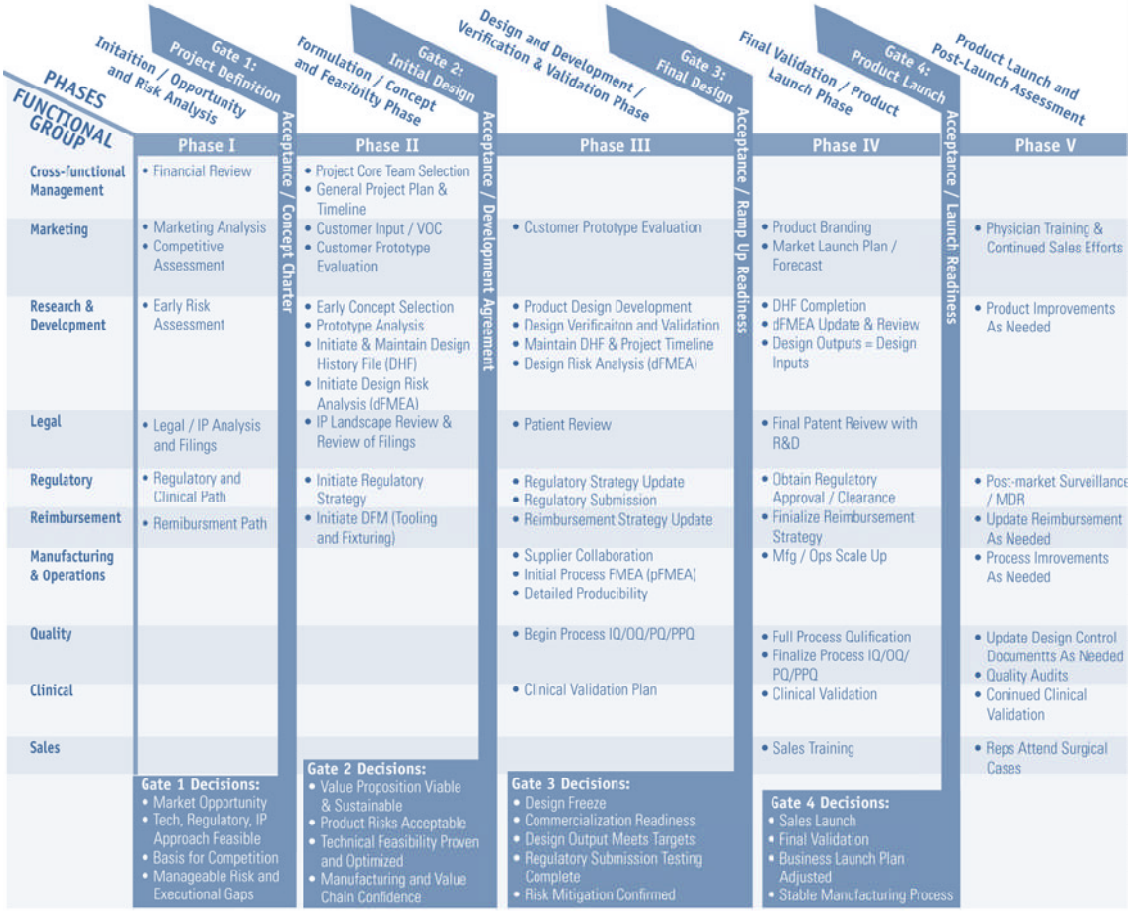


Figure 2-12: Generic medical product development cycle (Burt, V., 2009)

A generic framework for developing medical applications is presented which identifies the key phases and activities performed by functional groups. It's clear from figure 2.12 that the design and development phases play a fundamental role which in fact

provides the baseline point of product sustenance. Concept creation has been listed under the heading of initial design; most of the fundamental activities for concept creation have not been fully listed in figure 2.12. The model only provides a high level explanation of the key processes; therefore further investigation will be conducted.

Generic Concept Creation Process

For further reference a generic concept development process has been presented which highlights essentials aspects.

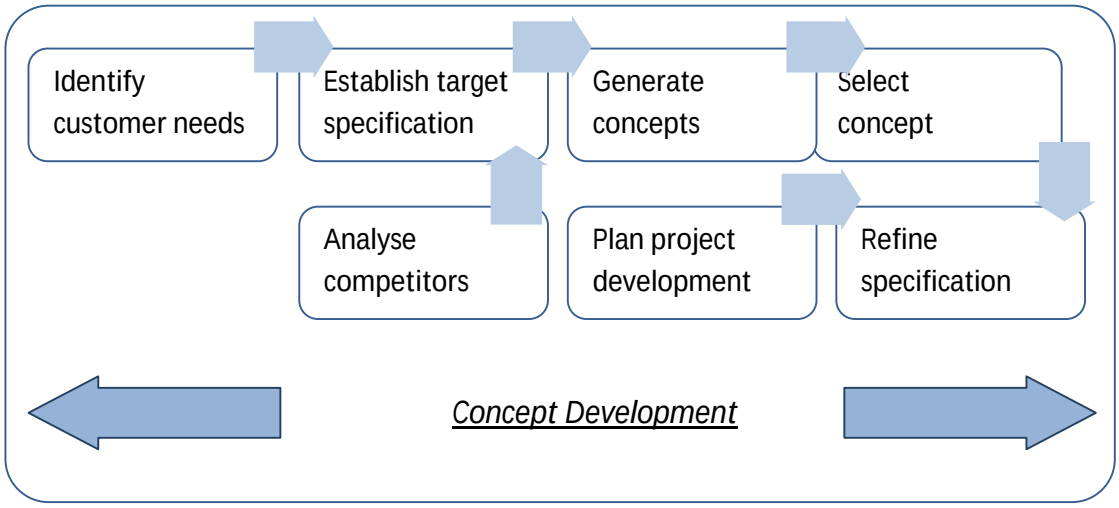


Figure 2-13: Generic concept development process (Riley, 2009)

- Identify customer needs: The process initiates by identifying customer needs, both apparent and hidden ones. This is achieved by performing thorough analysis of potential purchasers, observing market trend of competitors and focus groups. A list of the specifications are compiled and arranged in hierarchical comparative lists.
- Establish target specification: After the marketing department has established a rough specification of the product, engineers and designers get involved to specify the target specifications which primarily highlight technical constraints.
- Analyse competitors: This process is part of the establishing the target specification, its sole objective is to identify competitive products in development and in the market. Through the analysis downfalls and weaknesses of competitors is identified and list of improvements are proposed.
- Generate concepts: Designers and engineers take on board the specifications to develop technically feasible concepts. Engineers mainly focus on the structural aspects of the product while engineers primarily focus on the styling aspects of the product.
- Select concepts: Teams are usually arranged which can include executive and potential customer who then collectively review the concepts. The selection

process follows which ensures key concepts are further developed until they meet satisfactory demands.

- Refine specification: Up till this point a clear and more defiant image of the consumer would have been developed. The specification is refined through the consideration of additional aspects that might affect the foregoing activities.
- Plan project development: The final activities of concept development require the team to prepare a low level plan of execution which identifies the required necessities against the available funds.
- Overview: The key aspects of concept development have been discussed, the most interesting aspect discovered is that concept development initiates with identification of user needs. The misconception has been cleared out that concept development specifically deals with conceptualisation and styling of the product.

There isn't a complete concept creation model for the development of medical devices therefore the generic process discussed above will be the point of discussion. It will be adopted accordingly to suit the creation of medical applications.

The development of medical devices requires additional drivers and activities that must be made part of the initial processes. A generic concept creation model for the development of medical devices has been proposed. Key elements from the generic concept creation and generic medical product development process have been instigated.

Ameliorated Concept Creation process for Medical Applications

The proposed concept creation model has been dissected in to two sections; project initiation and project formulation. The first deals with the preliminary technical aspects that bring about the initiation of the project. The latter section deals with activities that formulate the concept creation. In addition to the generic concept creation model the following activities have been included:

Product risk assignment: medical devices are categorized in to three categories according to risk. High risk applications deal with life supporting, critical monitoring and energy emitting devices. Medium risk applications include diagnostic applications such as ECG, EEG, treadmills etc. Low risk medical applications are products whose failure or misuse is unlikely to cause any serious consequences such as breast pumps, surgical microscopes and surgical tables.

Perform early risk assessment: medical applications require a great deal of regularity assessment before any further development in to the project. Therefore this has been introduced earlier in the process to ensure the gateway towards concept generation is clear.

Develop core team: the introduction of a design/core team is voluntary in the generic concept creation process. However it has been made exceptional and mandatory to develop and assign individuals to form a team with predefined tasks to review and assess the progression.

Framework Adaptation to Suit a Virtual Environment

To successfully adapt the proposed framework in to a virtual environment it is essential to categories the activities by tool and techniques that can be used to replace the manual processes.

Identify customer needs: invite customers in to a virtual environment and use cyber group discussions to capture needs.
Develop core team: host online polls or conduct a query based character profile to select the most suited team members.
Generate concepts: use open source graphic applications to produce high quality vector based digital concepts.
Develop CAD Model: produce models using open source CAD packages and save in a universal format for global visualisation.

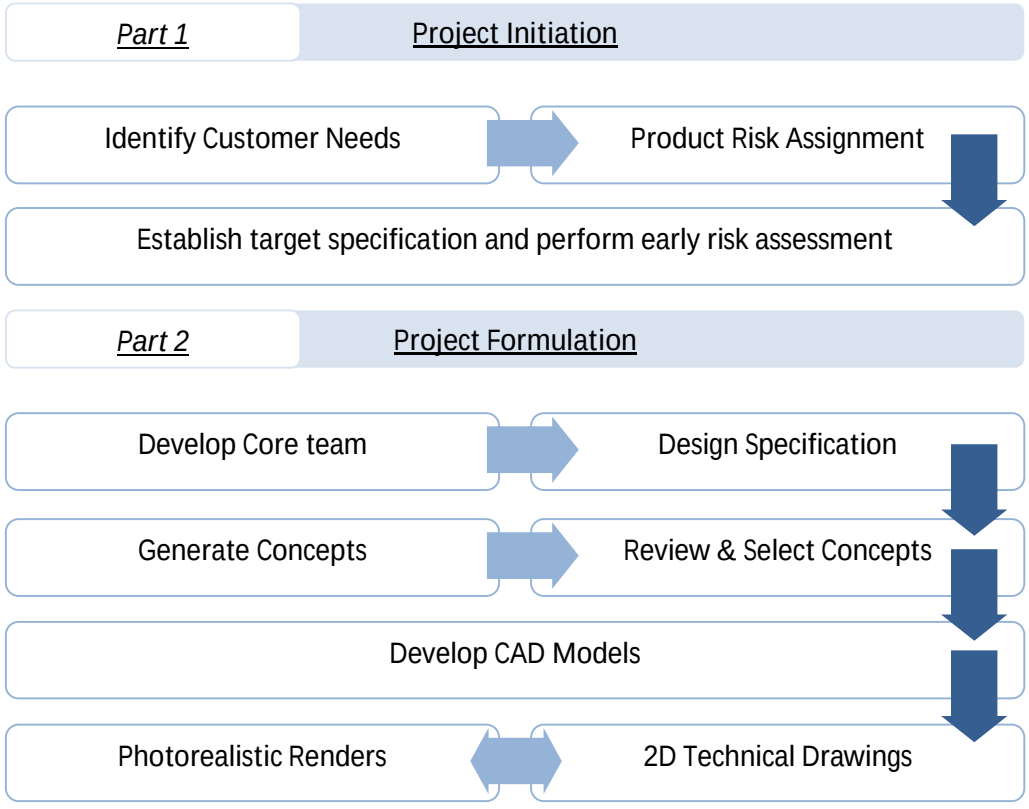


Figure 2-14: proposed concept creation model for medical device development

The section initiated with a generic overview of a typical product development model in comparison to a medical product development. A generic concept development framework was identified and analysed. Key aspects from the medical product development model were extracted and conflated to develop a concept creation process for medical application development in a virtual environment. The proceeding chapter will pay close attention in to technical issues such as legislations and selection of licenses to protect concepts.

2.17. Research Gap

The research that has been conducted in this chapter has provided a good understanding of the OSI. Though OS is being used in the medical sector no signs of using the initiative for developing physical medical products were found. The explanations gathered for the two comparative studies indicate the possibilities of using virtual web-based collaborative technologies in the creation of products.

All the papers reviewed had their strengths and weaknesses however not a single paper clarified the method they used for creating the product. It has been made clear that the opportunity for using OS in a slightly unorthodox way is still available. The web-based/virtual tools could be complimentary to aid in the development of sustainable medical products.

The web-communities response to the adoption of open source for product design showed an opportunity for a progressive study in this field. The Philips discussion was further supported with another independent poll which also showed positive results. However only one open source product design website was identified, the structure and some of its contents was critically analysed. A great deal of limitations were identified and addressed. The review ceased with an explanation of the importance of concept creation in the new product development process followed by a discussion of a typical medical product concept creation process. The final discussion proposed a generic medical product development process which could be used for this study – which was a result of thorough review of the literature.

2.18. Summary

The literature review has looked at the effects OS has had on the medical sector. OS medical applications were identified and described. Examples of products developed using opens were compared. An insight in to virtual collaborative development was provided. The chapter ceased with the development of a generic medical product development process to be used in a virtual environment. The commencing chapter will focus closely on the aims, objectives and the methodology of the project.

3. AIMS, OBJECTIVES & METHODOLOGY

This chapter commences with a clear definition of the research aims and objectives. Details of the scopes in-bounds and out-bounds are outlined followed by a descriptive explanation of the methodology constructed to ensure all aspects of the research requirements are addressed in a constructive and logical manner.

3.1. Aim

The aim of the research is to identify the potentials of using open source initiatives with a valid OS license to create medical concepts. This will be accomplished by developing a web-based, virtual framework that contains all the necessary tools, techniques and technologies to allow geographically disperse individuals to create concepts.

3.2. Objectives

Listed below are primary objectives that are required to suffice the research aims:-

- ⇐ Identify technicalities associated with the development of the open source virtual online web-based collaborative framework.
- ⇐ Develop and detail the specification for the web-based virtual concept creation framework.
- ⇐ Design the virtual environment to ensure it should encompass the required concept creation activities to accommodate the development of medical applications.
- ⇐ Investigation in to IPR protection and OS licences and proposing the most pertinent ways to protect the ownership of concepts.
- ⇐ Perform a live user trial by inviting specialist people to part-take in the initiation and the developmental stages of the project.
- ⇐ Design User documentation *(good practise guide)* is which can be followed by participants to successfully follow through the virtual environment.

3.3. Scope

Defining the scope is necessary due to the numerous directions this research can progress towards, by defining the in-bounds and out-bounds of the research will ensure the focus remains focalised. Details of the project limitations are as follows:-

3.3.1. In-scope

⇒ Collate and examine required literature from existing open source initiatives.
⇒ Aid in the development of the implementation of the framework via development of required graphics and contents.
⇒ Organise, participate and administer a live user trial of medical product on the virtual open source framework.
⇒ Analyse results of the live user trial focusing on the concept creation process.

3.3.2. Out-Scope

⇐ Develop a virtual framework that will include the complete product lifecycle.
⇐ Develop the framework to adapt to the concept creation process of non-medical products.
⇐ Physically produce a prototype of the finalised concept generated from the live user trial.

3.4. Research Methodology

A detailed account of the research methodology constructed to acquit the research objectives in the most effective and successful manner has been presented (see figure 3.1 for a graphical representation).

The methodology has been fragmented in to three sequentially phases; description of the activities is listed:

Familiarising Phase: research initiation

Literature review

- *Perform a state of the art literature review on open source initiatives, virtual collaborative design etc. to gain a good understanding of the current stance.*

Clarification of Project Deliverables

- *Elucidate project outputs and develop an organised plan which will ensure the execution of all activities within the project time frame.*

Instigating Phase: research development

This part of the research subsides in to a practical and theoretical part, both of which are parallel and complimentary to one another.

Practical aspect

- *Design the graphical illustrations of the virtual framework via script/storyboard and examine its feasibility.*
- *Develop the required graphics and contents for the framework.*
- *Refine the framework to eliminate discrepancies and errors.*

Theoretical aspect

- *Development of a generic concept creation model for medical device development*
- *Research in to open source applications that can be used during the concept creation process.*
- *Research in to the most applicable graphical and CAD file formats for the virtual environment.*
- *Base a study on OS licenses and select the most relevant license and develop terms and conditions for participants.*

Conjecturing Phase: research completion

Organising the live user trial

- *Organise and perform a live user trial for the development of medical initiatives hosted on the site by inviting colleagues and friends via email, word of mouth and Facebook connect. Who also invited their friends and family whom they were in touch with via social networking initiatives.*
- *Provide a brief explanation in to the projects hosted on the site and allow individuals to choose the preferred project.*
- *Encourage users to participate and contribute in the ideation section and discussion to instigate new ideas.*
- *Ask users to generate concepts by using the software available on the site, or any other software they own.*
- *The participants will upload/ share and discuss with the rest of the team their concepts- who will provide feedback.*

Assessment

- *Perform a detailed assessment on the output of the live trial through a semi structured questionnaire for the participants.*

Results compilation

- *Critically analyse the results from the questionnaire and provide statistical and graphical explanations of the results giving insight in to the key findings of the live user trial.*

Detailed Discussion

- *Accumulate all the research information from project initiation towards implementation and instigate a detailed discussion of the findings, thoroughly analysing the trends identified.*

Conclusion and further recommendations

- *Cease the research with a conclusion of the research and make further recommendations for future studies.*

3.5. Summary

In context the chapter has detailed the aims and objectives of the research. An insight in to the research methodology has been promulgated both literary and graphically. In continuation from this chapter the subsequent chapter will focus on outlining the role of concept creation in the product lifecycle; generically and explicit to the medical sector.

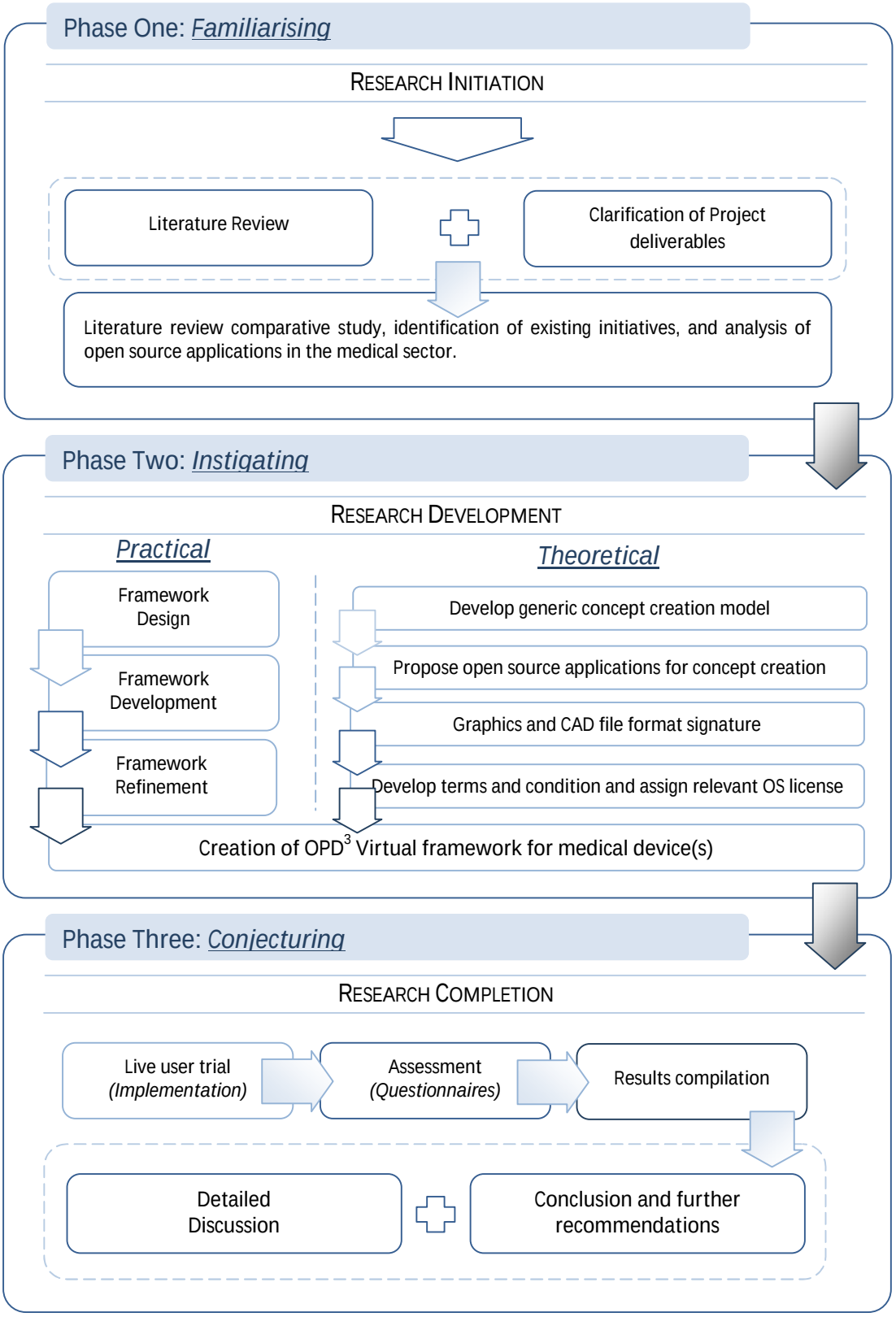


Figure 3-1: Research Methodology

4. OPEN SOURCE AND INTELLECTUAL PROPERTY

The preservation of rights to protect intellectual property in a collaborative environment is a serious topic. Introductorily a discussion on IP (intellectual Property) followed by its connectedness with open source is described. Commonly adopted OS licenses are discussed before a license if proposed. Terms and conditions for the web-based framework are developed in compliance with the license selected.

4.1. Property Definition

In today's developing society intellectual property is regarded as one of the most important aspects of the knowledge society. It serves as the regulatory bridge for businesses on the World Wide Web, areas such as: education, government politics and social engineering are also affected. The sublime concept associated with IP is based on acceptance and obedience to regulations that are to be socially adorned

Intellectual property is a singular aspect of the broad term 'property,' Donaldson and Donaldson and Preston (1995) sum up property as a cluster of rights, furthermore DeGeorge (1999) explains that rights are embedded in to social practices. The first principle of rights exclaims the ownership of something including fabrication, substitution and intake. The second principle of property is that the rightful owner has the right to omit others from use (Gauthier, 1986).

4.1.1. Definition of Intellectual Property

Lawrence (1996) explains that the ownership of anything invented by the mind, whether its ideas, thoughts, expressions or physiological impressions, come under intellectual property. Many argue that traditional concepts of property can be applied to intellectual property (Barlow, 1995). Enforcing rights of preservation on IP is vital, producing duplicates of originals can be easily achieved while distinguishing between the original and the duplicate would be impossible (Hinman, 2002). The notion of IP is rapidly growing to preserve the importance of resources within the knowledge society.

4.1.2. Limitations of IP

Johnson (2001) justifies the creation of a code created by a programmer, which is in effect the product of one's dedicated exploits as IP. Following on, it is known that IP produces more revenue via money, art and knowledge, hence an increase in social use. The major limitation of IP is in the situations where it is no longer able to produce revenues.

4.2. IP and the knowledge society

The knowledge society has had a great effect on IP; the development of information communication technology (ICT) has changed the way in which one must deal with IP. The creation of networks allows individuals and teams to share data and IP has caused problems in achieving these simple tasks.

The value of IP is rated in the billions of dollars, and it is expected to grow (Boyle, 2001). The ownership of artefacts produced by programmers is reserved as natural rights as it is a result of an extension of the programmer's physiological skills (Nissenbaum, 1995). The conflict arises between the programmer and the commercial vendor; however by claiming the development for social improvements via the motivation of the programmer's efforts the cost is minimized.

The breach of IP through duplications and manipulation of materials is on the increase by professionals and the general public, the common term for this is known as piracy. The interest of protecting IP is increasing in scale, in most cases it is big commercial vendors who are pushing for this move. Benkler (2001) argues that businesses are forming an economic ascendancy and ignoring the legitimate rightful stakeholder from the community. Furthermore the author holders the view that pirate software does not cause any social damage, because it would have never been bought.

4.3. Open Source and IP

The open source paradigm does not offer all the contributions made by users to the free public domain, however it is distributed under licenses. Different licenses provide different levels of freedom. OS software is also called 'free software' which means the user is able to read, modify and utilise the code according to their personal needs. However OSS has the potential to be sold therefore the licenses offer developers to make money though the main key is to deliver knowledge to the society.

OS artefacts do not conflict or question concepts of IP, because the developers are giving open rights to the public to use the knowledge created by one's own mental efforts. A state of breach will only occur should the author decide to reserve the right to make the contributions public.

The OS initiative is challenging IP; the central discussion is that developers are not gaining any financial benefits however this is turned down as the developers are doing it for knowledge. IP defenders emphasise the adoptability of rights to ensure a high quality product is developed, in fact OS artefacts output an equivalent if not a better quality than proprietary software.

In summary OS defends IP and ensures that goods can be produced without the external enforcement of laws. The acceptability of OS artefacts is much more than proprietary software. Till date the winners have been the owners of IP, the social structures of OS has changed the direction, now making consumers the winners over large corporate.

4.4. Open Source Licenses

In continuation of the previous section an insight in to OS licences. An explanation of the common OS licences is provided; an exception to a selection will be made for the proposed medical initiative. Its potential benefits will be assessed prior to effectuation.

There are many OS licences which have been certified and approved by the OSI (Open Source initiative) of which the most common ones have been listed.

4.4.1. General Public License

GPL is an open source license that is widely used within the community; it was introduced by the FSF (Free Software Foundation), typically it inherits characteristics from many licenses. By modifying an artefact under GPL the user is required to open the contributions (see Ueda, 2005). To avoid the inheritance 'virus' one may use the LGPL (Lesser General Public License). Under the GPL users are able to review, use, modify and credit the contributing authors; all modifications must be made publicly known.

4.4.2. Mozila Public License

Some licences have been created by the community while others have been created by companies; MPL is an example of a license developed by the community. It allows one to open freely, copy, modify and distribute the artefact. IBM also has a public license, this particular license is less more constrained from the rest as it contains a section on patent, Ueda (2005.

4.4.3. Creative Commons Licence

The attributes of the creative commons licence make it most flexible and dynamic, it contains all the flexible rights offered by the LGPL, GPL and MPL but also many other licences. CC allows one to selectively select attributes which can be assigned to the whole or a part of the artefact giving the freedom to protect contributions according to one's personal needs.

4.5. License selection for the Medical Initiative

The commonly adopted licenses in the open source paradigm have been assessed. The LGPL, GPL and MPL licenses have specifically been developed for software code use, manipulation and re-load.

The medical initiative will be based upon the contributions of ideas, concepts and knowledge that has the potential to be physically produced i.e. CAD models. The most applicable license in this case would be the creative commons, reason being is that though an author has made contributions they are still granted the rightful access to protect their contributions.

4.6. Creative Commons License

A detailed explanation of the CC license attribute has been discussed below, followed by justifications of how the available features may be beneficial to the participants of the Medical Initiative.

Figure 4-1: Creative Commons logo

The Creative Commons license offers four main licenses which can be applied on to published work. Participants in the initiative will be given the flexibility of selecting the most suited license on their contributions reserving rights wherever need be (Creative Commons, 2009).

Creative Commons: Attributions

The attributions license allows the third party to distribute, remix and modify the work at educational and commercial level providing the original author has been accredited for the original creation. This is seen as the most accommodating Creative Commons license.

Figure 4-2: Creative Commons attribution logo

Creative Commons: Share Alike

This particular license allows users to remix and modify and accredit the original author for personal and commercial use. However any modifications made will carry

the same license as the originals as prescribed by the author. All derivatives will be made publicly available. This particular license can be compared to the GPL OS license.

Figure 4-3: Creative Commons share alike logo

Creative Commons: Attribution, No derivatives

This license allows one to redistribute the artefacts for personal and commercial usage, providing it's passed down unchanged in anyway.

Figure 4-4: Creative Commons attribution, no derivatives logo

Creative Commons: Attribution, Non-Commercial

Attribution non-commercial license allows others to remix and modify the data for non-commercial gains, the must acknowledge the original author. However the modifications they make do not have to conform to the original terms and conditions set by the initiator.

Figure 4-5: Creative Commons attribution, non-commercial logo

Creative Commons: Attribution, Non-Commercial, No Derivatives

This particular CC license is the most restrictive; it allows redistribution of the work. Third party users can download and reference back to the original download source but under no circumstance is the information to be modified or used for commercial purposes.

Figure 4-6: Creative Commons attribution, non-commercial, no derivatives license

4.7. Author's recommendation

The scope of creative commons as compared to other open source licenses has been discussed. In comparison to traditional open source licenses the flexibility of creative commons license a great deal can be achieved. In an open source environment where enriched ideas are being exploited in the development of medical products, without a doubt creative commons would be the most suited license.

4.8. Terms & Conditions

The terms and conditions have been encrypted as an agreement between the initiative and any corresponding participating body. The terms and conditions are subjugated in to five sections: introduction, participation, intellectual property, contents and termination.

⇒ Introduction

A welcoming statement is provided followed by instruction to register as a single user, in case of registering for an organisation, users are told to contact admin.

⇒ Participation

Methods of registration and seeking lost passwords are outlined followed by rulings on multiple user accounts.

⇒ Intellectual property

Information on the creative commons license is provided and adherence to the project initiators terms and selection of license attributes are mentioned.

⇒ Contents

The responsibility of assuring the contents uploaded on the site database must be original and must not infringement any laws. The consequences of breaching this rule have cleared out.

⇒ Termination

The correct procedure of termination has been explained, and how to put requests for the removal on uploaded contents and its procedures are covered.
(See appendix A for the full terms and conditions)

4.9. Summary

The importance of IP and its connectedness with OS has been thoroughly recorded. Details of common OS licences have been listed followed by an explanation of the different creative common licences that are available. The chapter finished with the compilation of the terms and conditions that will be used for the initiative.

The proceeding chapter will use the concept creation model from chapter 4 to develop a script for the framework. The process will be designed to adhere with the creative commons license; simplistically allowing users to create, share, modify and re-use contents for the hosted project(s).

5. FRAMEWORK DESIGN AND DEVELOPMENT

Primarily, the focus of this chapter is to elucidate the design and development of the virtual framework for concept creation. UML (Unified Modelling Language) Use Case diagrams and sequence/activity diagrams have been used to capture the requirements and activities of the system. The concept creation model developed in chapter 4 has been used to develop the initial structure of the framework. Detailed explanations of the activities are provided. The chapter ceases with screenshots of the fully developed framework.

5.1. UML Use Case and Sequence/Activity Diagrams

The section and its subheadings aim to explain to capture the system requirements via UML Use case diagrams. Furthermore, sequence/activity diagrams are used to highlight key activities involved in the concept creation process from a 'new comers' perspective.

5.1.1. Developing Use Case Diagrams

UML Case diagrams have been used to capture the specifications of the system, and delineate the interaction between project initiator and the coinciding users for concept creation process.

UML use cases were selected as they are commonly used amongst software and web developers in capturing and logically displaying system requirements. Other benefits of UML diagrams are that they are easily understood and provide sufficient guidelines for implementation.

UML diagrams have been induced for all the stages of concept creation which were established in chapter 2.16. Figure 5.1 displays the use case for the overall system, the use case diagrams of the inner process can be found in Appendix B.

The Use case diagrams were developed initially through the understanding of literature, for example the medical concept creation model and the available tools for the open source initiatives provided the foundation. With a thorough understanding of literature and personal experience the author brainstormed, designed and developed the possible structure of the system, bearing in mind the internal and external influences on the system.

5.1.2. Use Case Diagrams

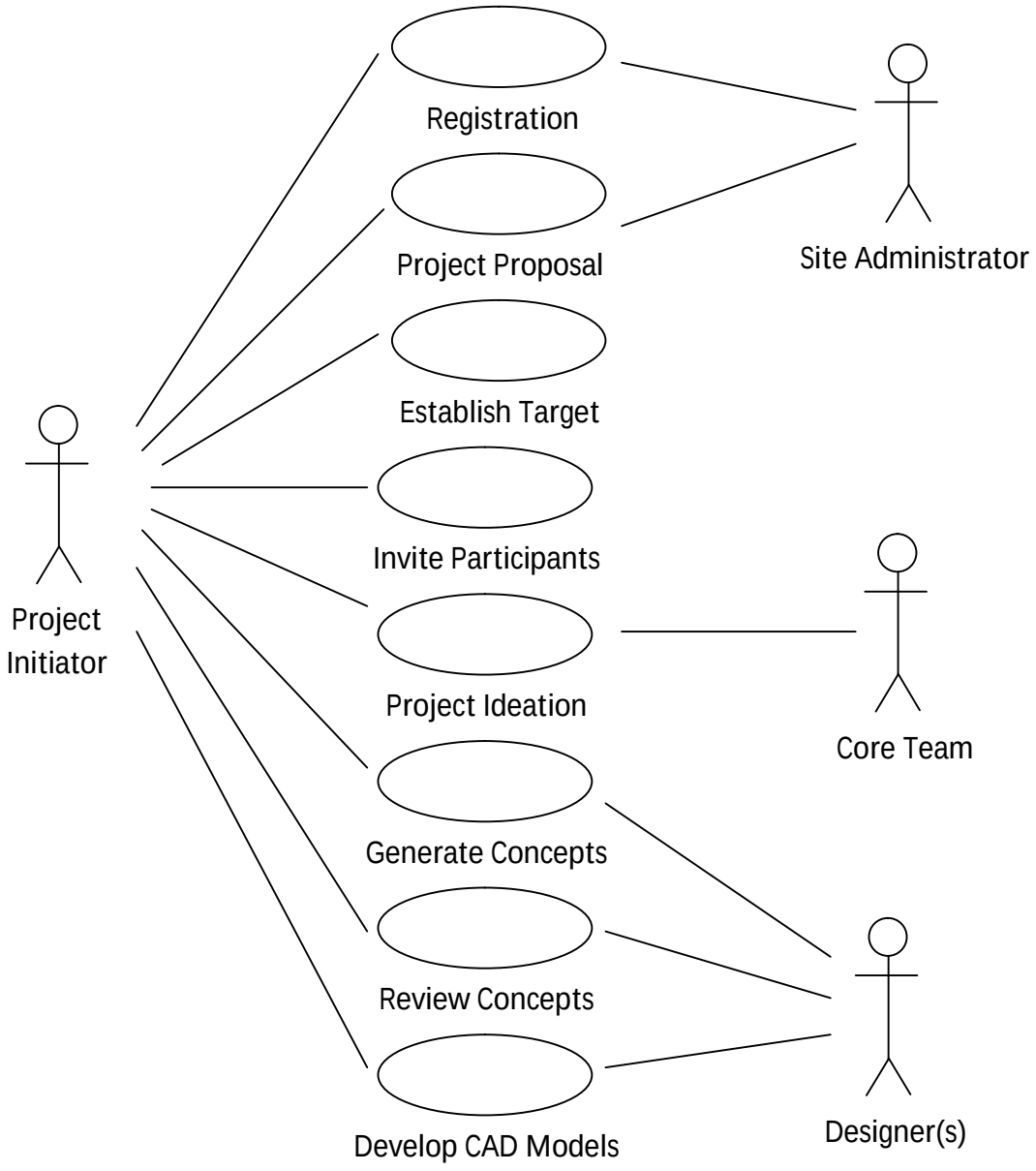


Figure 5-1: Use Case for concept creation process on the OPD[3] site

Registration: The user must register on to the initiative in order to gain access to the system. After completing the required form the site administrator will grant access to the site providing the necessary requirements are met.

Project proposal: The use case for this factor will require the user to log on to the system, complete the proposal form and submit it. Participation from the stakeholders and experts is required in the composition of the proposal.

Establish Target: The use case for establishing target requires the identification of the market opportunity followed by manageable risk. Once a technology analysis has been performed the user is required to review the lead.

Invite Participants: This use case identifies the need to invite and develop the project community.

Project Initiation: From the use case the core team and general participations will clarify the problem and establish the design specification.

Generate Concepts: Use case for generating concepts requires the development and validation of a specification followed by concepts which are then to be uploaded on to the system.

Review Concepts: The need to develop review intent and assign a strategy to be conducted by the review team to analyse concepts for interpretation were derived from this use case.

Develop CAD Models: Developing CAD models by selecting concepts and then producing CAD models and uploading them on to the system was extracted from this use case.

5.1.3. Sequence/Activity Diagram

UML Sequence/activity diagrams are used to display workflows and activities with the support of actions. These drawings are commonly used to display operational aspects of the system.

Sequence/activity diagrams have been considered for to display typical activities a new comer should follow. The basic process though captured in the use case required additional explanation from a user perspective.

Figure 5.2 presents the activities one must perform to successfully complete the concept creation process on the site.

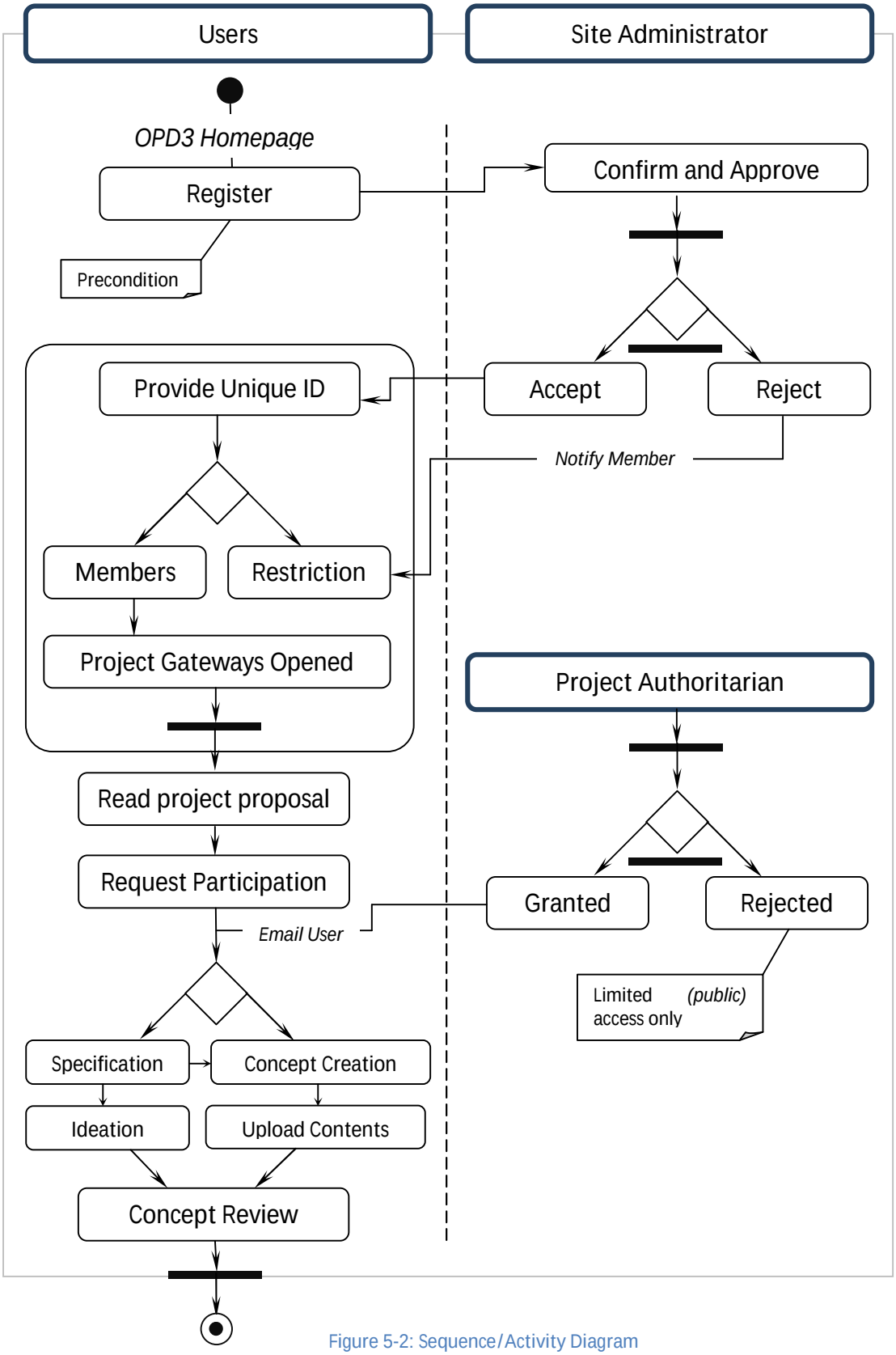


Figure 5-2: Sequence/Activity Diagram

5.2. Concept Creation Process Organised

Presented is an organised revision of the concept creation process which was developed in chapter 4.4 (see figure 5.3)

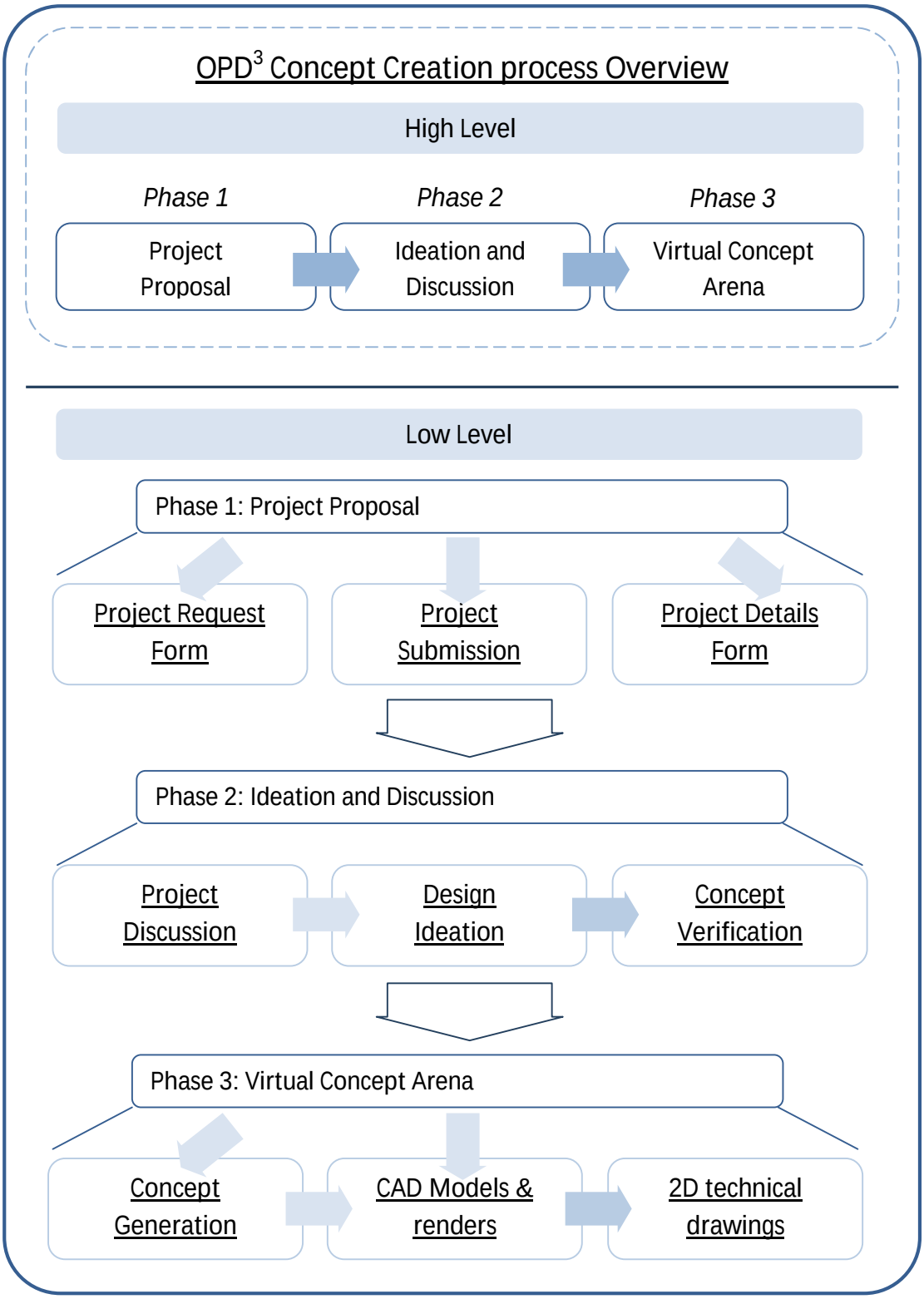


Figure 5-3: OPD^3 Concept Creation Process

5.2.1. Activity Explanations

Based on the activities discussed in figure 5.3 a detailed explanation of the internal processes is listed in table 6.1.

		Principle Functions
Activities	Project Proposal	
	Project Request Form	Users must complete a request form by which they can list the market opportunity, execution gaps, managerial risk(s), customer needs and technical/functional/environmental requirements.
	Project Submission	After completing the request form, participants should be able submit the proposal for authorisation by the administrator.
	Project Details Form	Upon validation and acceptance of the project proposal, the details will be made publicly available for all the participants of the project. The team will be able to discuss and collectively establish a target specification.
	Project Ideation and Discussion	
	Project Discussion	A main site portal should be available for each of the hosted projects which will serve as the main meeting point for all participants. General discussions of the project must be hosted and recorded in the portal for future references.
	Design Ideation	Good concept development comes through successive, cooperative and collective discussions. The annotations provided with the designs must explicit the functionalities of the concept. A tool must be available for users to view the concepts, annotations and download the designs.
	Concept Verification	Progressive design requires concept verification against the design specification. A discussion portal must be made available for the designers to openly undertake meaningful discussions to verify the concept feasibility.
	Virtual Concept Arena	
	Concept Generation	Users may download the given OS applications to generate digital concepts or use the collaborative sketching tool (online) to generate concepts. Participants should also have the function to upload scanned concepts.
	CAD Models and renders	A section should be made available for users to upload high quality renders of the CAD models. CAD files must be made available in universal formats for all the participants for visual and modification purposes.
	2D technical Drawings	A section must be provided to visualise and download 2D technical drawings which will be used for design feasibility and assessing production feasibility.

Table 5-1: Details of activities

Nine of the major activates followed by key functionalities have been discussed; these will now be incorporated in to suit a structured environment.

5.3. Script

Scripts for all of the pages within the concept creation process have been discussed in continuation from table 5.1. Features have been identified and discussed, including: tools, technologies and techniques that are to be incorporated.

5.3.1. Project proposal

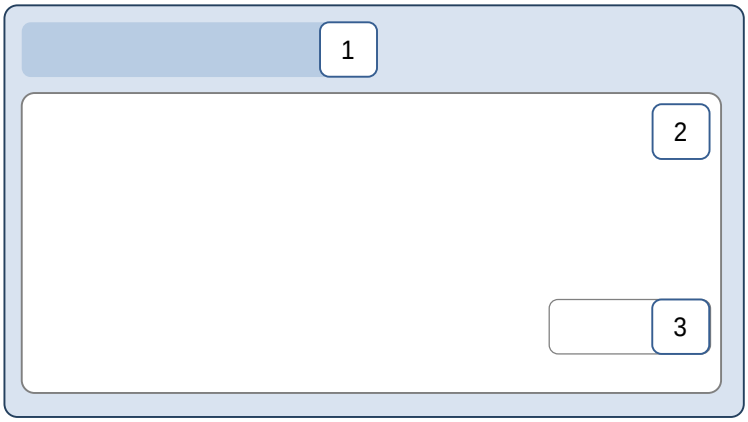
<table>
<tr><td colspan="2">Purpose: project proposal form to be filled in by a registered user to initiate a project.</td></tr>
<tr><td>Site Screen</td><td>Feature(s)</td></tr>
<tr><td> 
</td><td>(1) Device risk levels
(2) Project proposal form
(3) Submission button</td></tr>
<tr><td colspan="2">Feature Explanation:-</td></tr>
<tr><td>1</td><td>All medical applications are categorised in to classes, based on risk. The project initiator must clearly indicate the risk level of the proposed application.</td></tr>
<tr><td>2</td><td>The project proposal form is to constitute the following sections: [1] project title, [2] purpose for use, [3] scope, [4] stakeholders, [5] application overview, [6] functional requirements, [7] usability, [8] technical requirements, [9] environmental requirements and [10] required support.</td></tr>
<tr><td>3</td><td>Upon completion of the form a feature/button must be available for the user to submit the proposal to the site administrator.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">After completing the form, the project initiator should be in position to contact the site administrator to discuss the potentials of the project. Once an agreement has been made the project will be made visible for public viewing.
This is a security feature that must be adhered to ensure legitimate and genuine projects are uploaded. Following the agreement the counter activity to invite individuals to participate in the project. Registered users will then be referred to the project details page which will serve as the principle discussion point.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">This page is expected to be basic in terms of layout and structure, the expected format is to be a table in which the data must be fed in to. Therewith a validation feature must be enabled to ensure mandatory sections within the table are completed prior to submission. Additionally, a drop down menu could be used for the device risk selection.</td></tr>
</table>

Table 5-2: Project proposal script

5.4. Project Ideation and Discussion

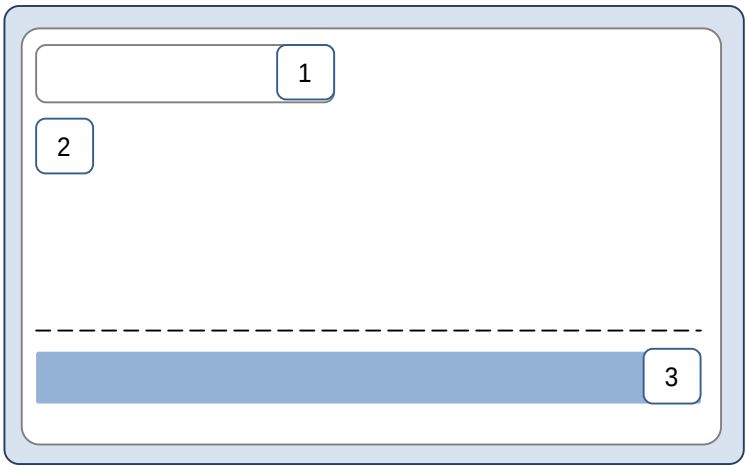
<table>
<tr><td colspan="2">Purpose: the main portal that will be discussion point for all the participants.</td></tr>
<tr><td>Site Screen</td><td>Feature(s)</td></tr>
<tr><td> 
</td><td>(1) Project Image
(2) Project details
(3) Discussion portal</td></tr>
<tr><td colspan="2">Feature Explanations:-</td></tr>
<tr><td>1</td><td>Each project can be customised with an image or the host may want to use a participating parties logo i.e. Bupa, NHS etc</td></tr>
<tr><td>2</td><td>This section will be used to display the project details which are to be retrieved from the project proposal form. The data is then to be organised in a constructive and coherent way under the following headings: [1] setting the scene, [2] project requirements and [3] Additional information.
All participants will refer to this during the course of the development of the project. It will serve as the project specification and give guidelines throughout the progressive stages.</td></tr>
<tr><td>3</td><td>Below the project details, a commenting feature must be installed which will allow users to make comments on the projects proposal and make relevant discussions.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">⇒ Amend the project proposal
⇒ Undertake research in to a specific area related to the project
⇒ Perform Concept ideation
⇒ Design and upload concepts to the virtual arena.
⇒ Collectively generate digital concepts using the collaborative feature.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">⇒ A graphical image can be used to customise the project.
⇒ A scroll menu could be used to confine the project details to ensure the page is balanced in terms of the contents.
⇒ A flash based commenting feature should be installed to allow users t make comments, upload images, hyperlinks and external URLs.
⇒ RSS feeds could be used to keep all the participants up to date with all the discussions taking place on the portal.
⇒ Users should be able to bookmark and email the details to invite others to the project.</td></tr>
</table>

Table 5-3: Project ideation and discussion script

5.4.1. Collaborative Sketching

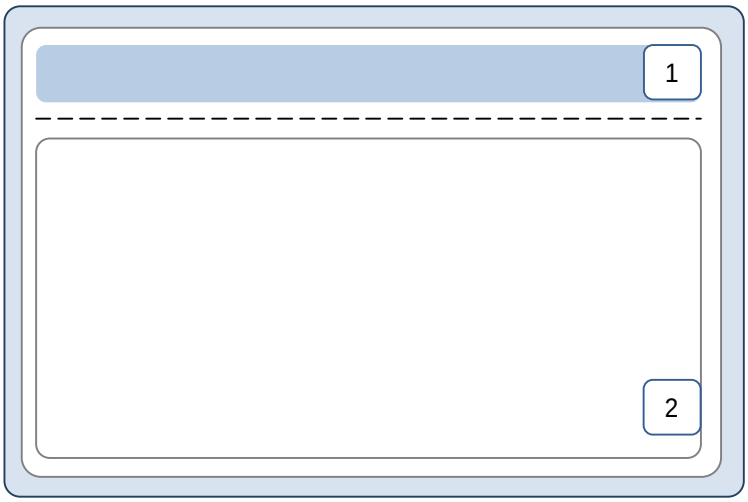
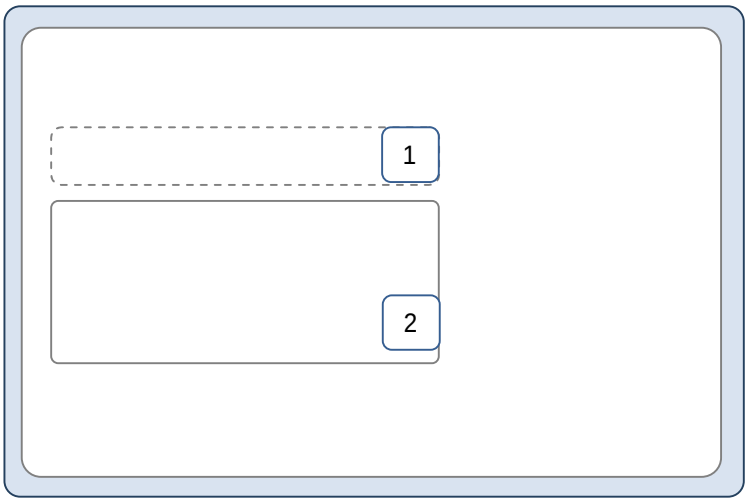
<table>
<tr><td colspan="2">Purpose: allow users to collectively design graphically online.</td></tr>
<tr><td>Site Screen</td><td>Feature(s)</td></tr>
<tr><td rowspan="2"> 
</td><td>(1) Navigation</td></tr>
<tr><td>(2) Flash based graphical application.</td></tr>
<tr><td colspan="2">Feature Explanations:-</td></tr>
<tr><td>1</td><td>Designers can use the navigation buttons to view sketches produced using the tool. They should also use these navigations to create and save new sketches.</td></tr>
<tr><td>2</td><td>The main part of the page will inhabit the flash based graphics application that will be used to generate digital concepts.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">Users may decide to save and revisit and modify designs that have been created on the application. Subsequently they could upload those concepts straight on to the virtual arena for group viewing and assessment.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">⇒ The main focus of this page is the hosting of a flash graphics application; it should include the necessary tools as found in commercial graphics applications. It should allow users to create modify and delete on multiple layers, tools such as brushes, texts and basic shapes should be available.</td></tr>
</table>

Table 5-4: Collaborative sketching script

The collaborative sketching tool is to be used a supplementary application for users who have restricted access to download and install graphics applications. By utilising this application will provide them with sufficient tools and techniques required to generate successfully high quality digital renders.

5.4.2. Multi Content Uploading Portal

<table>
<tr><td colspan="2">Purpose: an uploading portal which is to be used to upload contents to the site.</td></tr>
<tr><td>Site Screen</td><td>Feature(s)</td></tr>
<tr><td rowspan="2"> 
</td><td>(1) Selection Box</td></tr>
<tr><td>(2) Content details form</td></tr>
<tr><td colspan="2">Feature Explanations:-</td></tr>
<tr><td>1</td><td>The selection box should allow user to select whether they are uploading a [1] concept, [2] CAD render, [3] 2D technical drawings or [4] CAD model.</td></tr>
<tr><td>2</td><td>The uploading portals should allow users to upload contents to the respected databases. It is to be segregated in to two main sections, as listed below:

<u>Concept, Renders and 2D technical Drawings</u>
⇒ Users should be able to upload all image formats
⇒ A text should be available for users to provide detailed descriptions of the concepts and renders.

<u>CAD model</u>
⇒ The system should accept VRML and U3D files
⇒ Original files should be uploaded with instructions and details in a compressed file.
⇒ Users should be able to list the version, title and details of the upload.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">After uploading the next activity would be to verify the upload by visiting the virtual arena.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">⇒ A selection box will be used to select the desired area for upload.
⇒ A validation measure will need to be in place to ensure the correct file formats are uploaded.
⇒ For concepts, renders and 2D technical drawings all image formats will be accepted
⇒ For CAD models, the user must upload a VRML (*.*wrl) and U3D (*.*PDF) file as well as the original file in a compressed file either as a (*.*zip or *.*rar) format.</td></tr>
</table>

Table 5-5: Collaborative sketching script

5.4.3. Virtual Arena

<table>
<tr><td colspan="2">Purpose: display uploaded contents i.e. concepts, renders and 2d technical drawings.</td></tr>
<tr><td>Site Screen</td><td>Feature(s)</td></tr>
<tr><td> 
</td><td>(1) Flash based Content Viewer</td></tr>
<tr><td colspan="2">Feature Explanations:-</td></tr>
<tr><td>1</td><td>The virtual arena revolves around a flash based interactive content viewer that will display the uploaded images including the descriptions.
Users will be able to interact with the uploaded contents and a function for downloading should be made available.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">After visualising the contents the users are expected to rate and discuss the concepts in the main discussion portal.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">⇒ The flash- based viewer should be interactive; users should be able to [1] pan between the contents, [2] zoom in and out, [3] view descriptions for each of the contents and [4] download the selected content(s).</td></tr>
</table>

Table 5-6: Virtual arena script

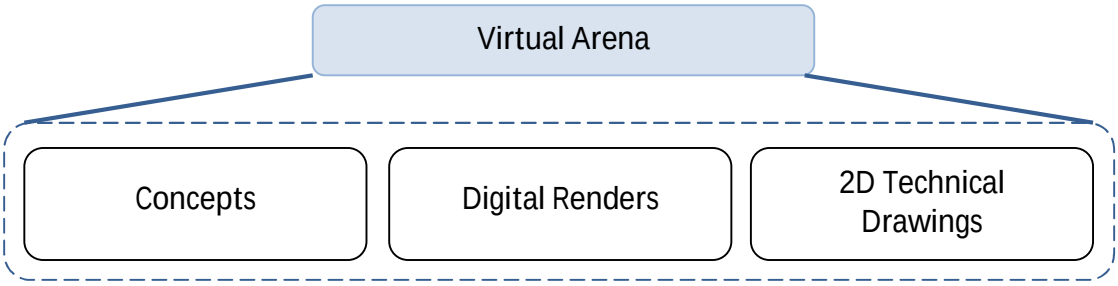
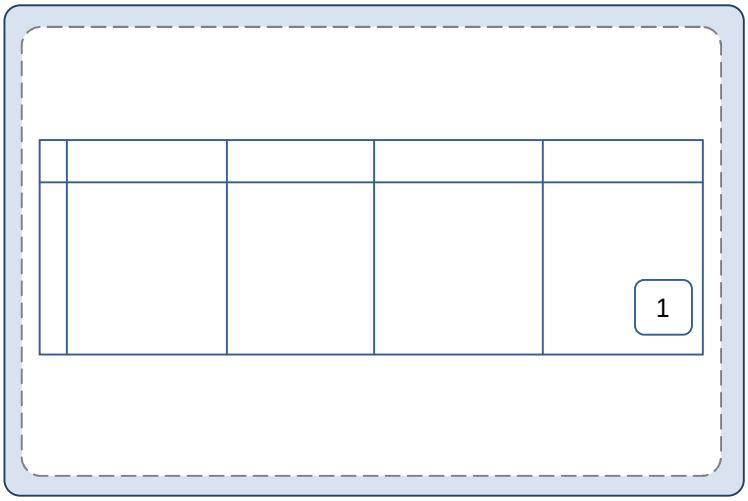


Figure 5-4: Virtual arena construction

The VA is a construction of three portals, each hosting its respected contents however the structure, layout and technologies will be the same.

5.4.4. CAD Visual and Management Portal

<table>
<tr><td colspan="2">Purpose: Visualise CAD models using universal file formats and make reviews.</td></tr>
<tr><td colspan="2">Site Screen | Feature(s)</td></tr>
<tr><td colspan="2"> 

(1) CAD Model Management Table</td></tr>
<tr><td colspan="2">Feature Explanations:-</td></tr>
<tr><td>1</td><td>⇒ The table has been designed to all the ease of managing CAD files through the developmental stages, users will be able to control the versions of the files and ensure recent models are viewed.
⇒ The structure of the table ensures no restrictions are applied to the limits of content download. Participants have full access to visualise and download the entire contents within the table.</td></tr>
<tr><td colspan="2">Counter activity:-</td></tr>
<tr><td colspan="2">Users may verify all the hyperlinks generated to see if the VRML and U3D files are functioning properly.</td></tr>
<tr><td colspan="2">Tools, techniques and technologies used on the page:-</td></tr>
<tr><td colspan="2">⇒ All the CAD uploads are in universal file formats: VRML and U3D, users will be able to view the models directly within their internet browsers.
⇒ By downloading the U3D file users will be able to annotate and review the PDF CAD files to give feedback to the CAD modeller.
⇒ A template</td></tr>
</table>

Table 5-7: CAD portal script

5.5. Framework Implementation

The script discussed in section has been used as a guideline to develop the website CC framework. The framework of the site alongside the recommendations of the tools and techniques to be used was proposed by the author. The implementation and website construction was done by Ken Mortimer.

5.5.1. Template Creation

Templates have been created to ensure a consistent and standardised organisation of the uploaded information. As listed in the terms and conditions, users are obliged to use the templates for uploading contents of the site.

5.5.1.1. Design Content templates

The concepts, renders and 2D technical drawings share a similar layout and structure of the templates. Users are required to note the date, the author(s) and the project details in addition to other information.

5.5.1.2. CAD Model Management Template

The users must us the '*PDF CAD Template'* to place the U3D file. The second template is used to provide the CAD developers with the required information on the original file such as software package used, number of parts, part functions etc.

Users can easily download the templates from the sites downloads section. The design templates are available in PDF and JPEG format, the CAD management template is available in PDF and Doc format.

5.5.2. Framework Implementation

The commencing section details the framework of the site; screenshots have been provided to identify key pages in the concept creation process. Additionally, key features have been highlighted numerically and discussed.

5.5.3. Homepage

Figure 5-5: OPD^3 Homepage

1. Principle site navigations
2. OPD^3 medical initiative details (flash banner) providing basic site information.
3. Provide users with latest news and updates of the site.
4. Project selection menu, users can view three new projects in all three categories.

5.5.4. Project Proposal Form

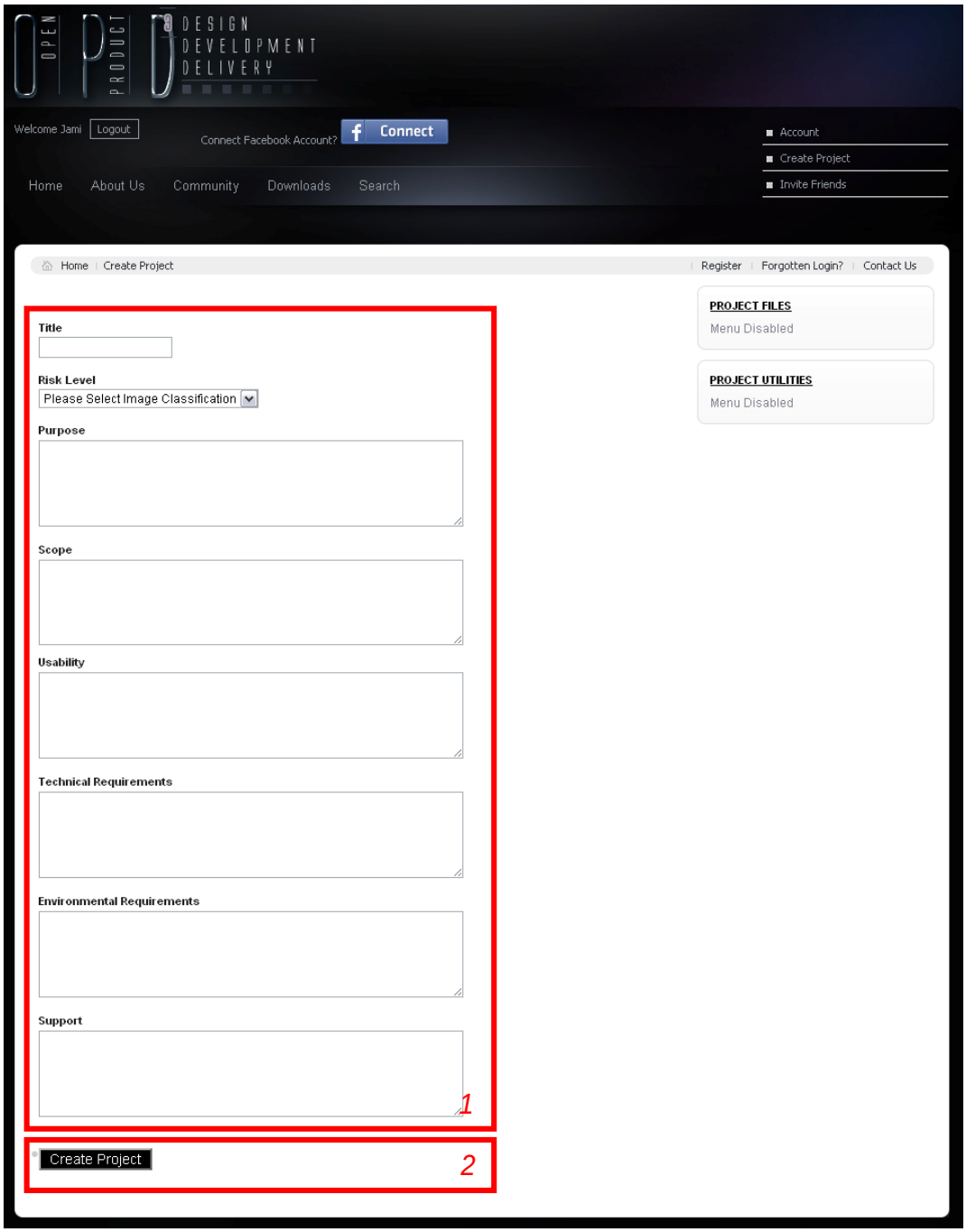


Figure 5-6: Project proposal form

1. Project proposal form which is to be completed by the project initiator, all fields are mandatory.
2. By clicking 'Create Project' the author will submit the project to the site administrator for approval.

5.6. Project Ideation and Discussion

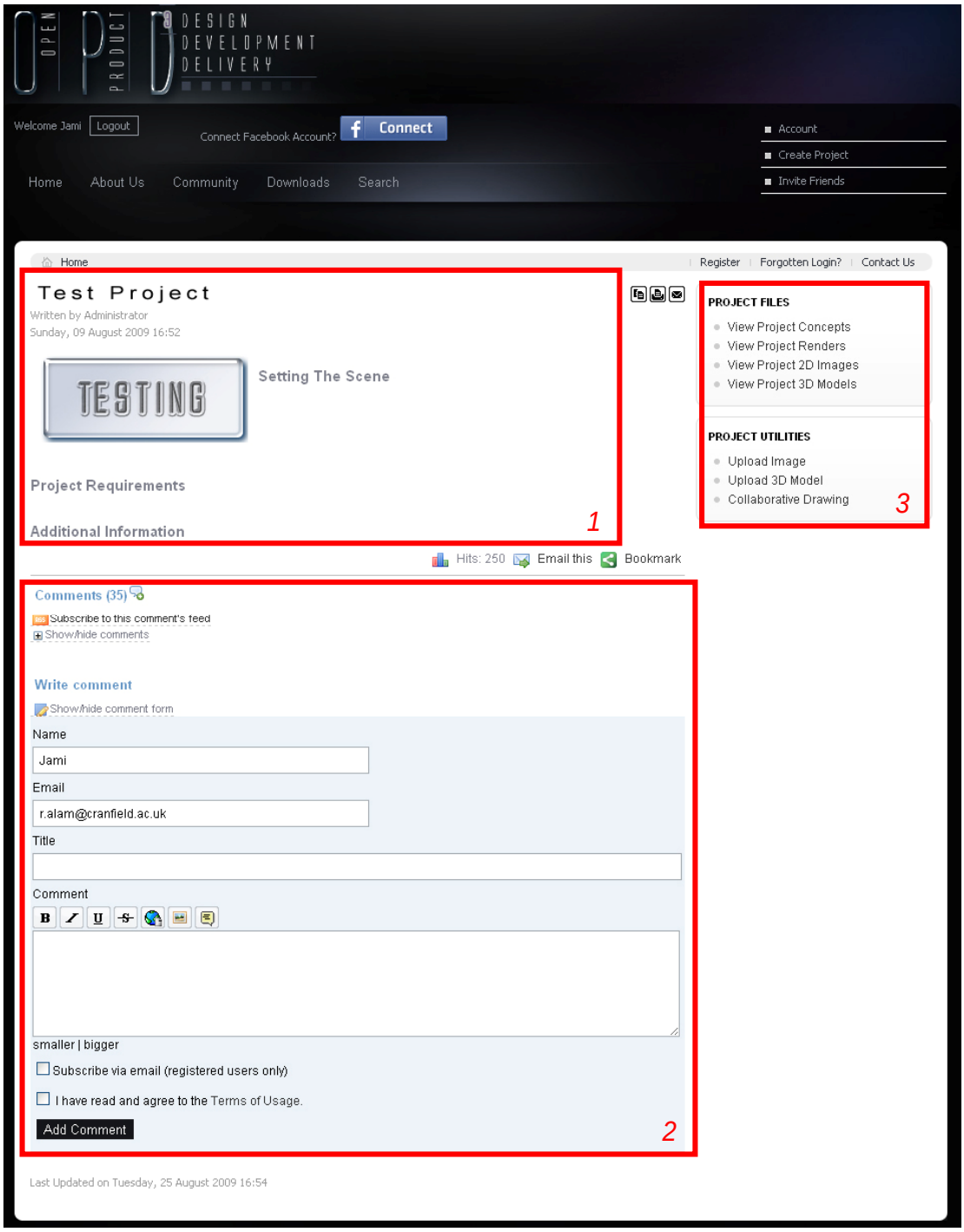


Figure 5-7: Project ideation and discussion page

1. Project details (as retrieved from the project proposal) are presented for all participants.
2. Comments form which users must fill to add comments and subscribe to RSS feeds.
3. Project utilities and files are now activated which allow access to the virtual arena.

5.7. Collaborative Sketching

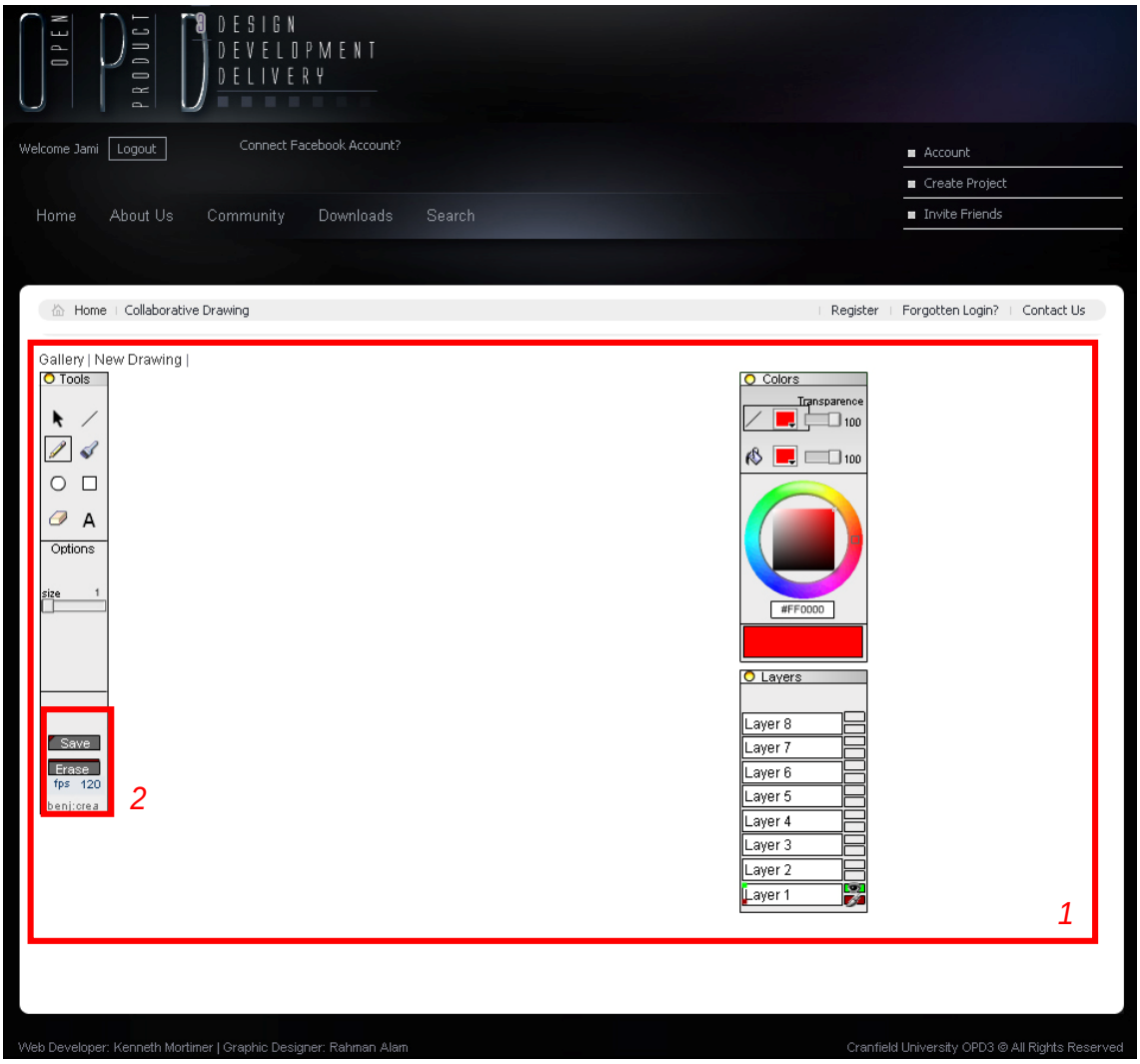


Figure 5-8: Collaborative sketching flash portal

User can access the collaborative sketching flash portal by selecting collaborative sketching from the project utilities menu as highlighted in the previous section.

1. The flash based collaborative sketching environment is visible with all the required graphical tools to create and modify digital renders.
2. The designer will use the following buttons to save the session, which will be recorded on to the project database for all participants to visualise and comment.

5.8. Uploading Contents: *Concepts, renders and 2D technical drawings*

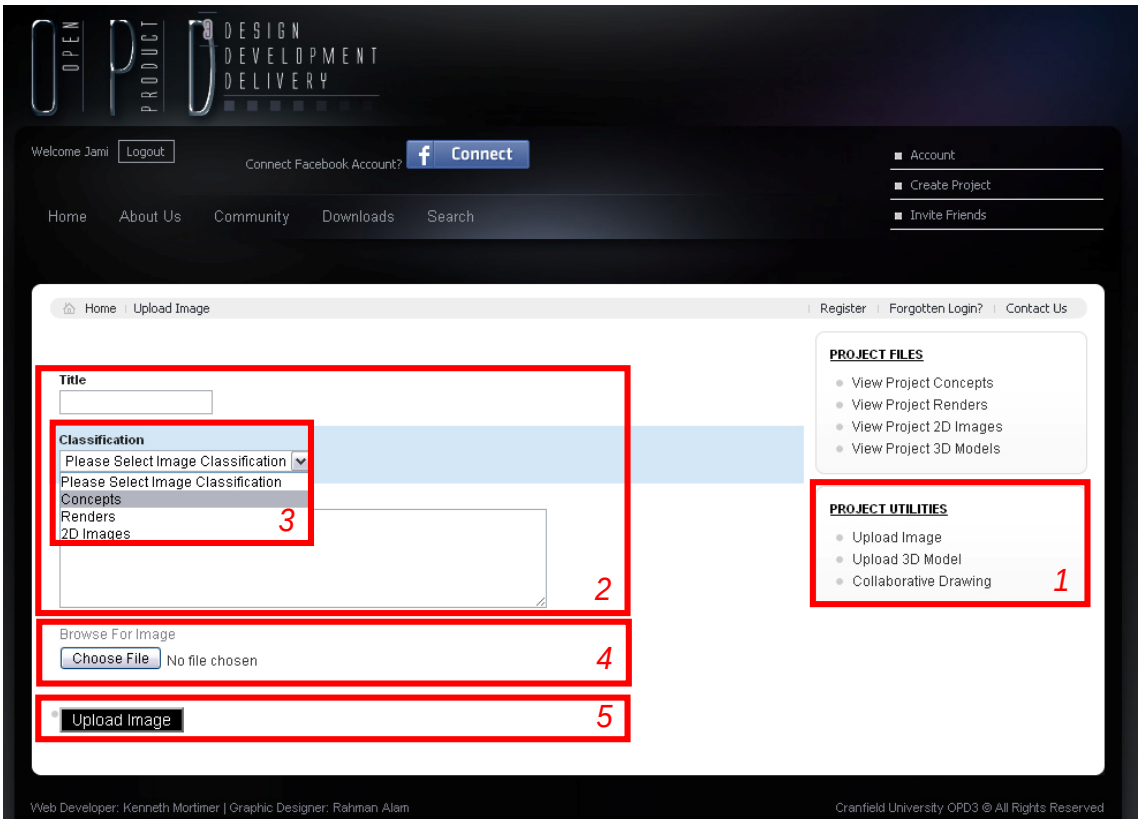


Figure 5-9: Uploading contents page

1. By selecting the *'Upload Image'* from the *'Project Utilities'* from any of the pages the user will be exposed to the contents upload page.
2. This particular form requires the user to give the file a title, select whether it's a concept, render or 2D image and provide a description.
3. The user may select the respected category by clicking the scroll button.
4. By clicking the *'Choose File'* button will allow the user to browse for an image file for uploading.
5. By selecting *'Upload Image'* the system will transfer the image on to the project database from which it will re-transfer it on to the virtual arena.

This contents upload page is only suited for concepts, renders and 2D images, the CAD upload requires additional fields therefore it has been made independent from this page.

5.9. Uploading Contents: *CAD models*

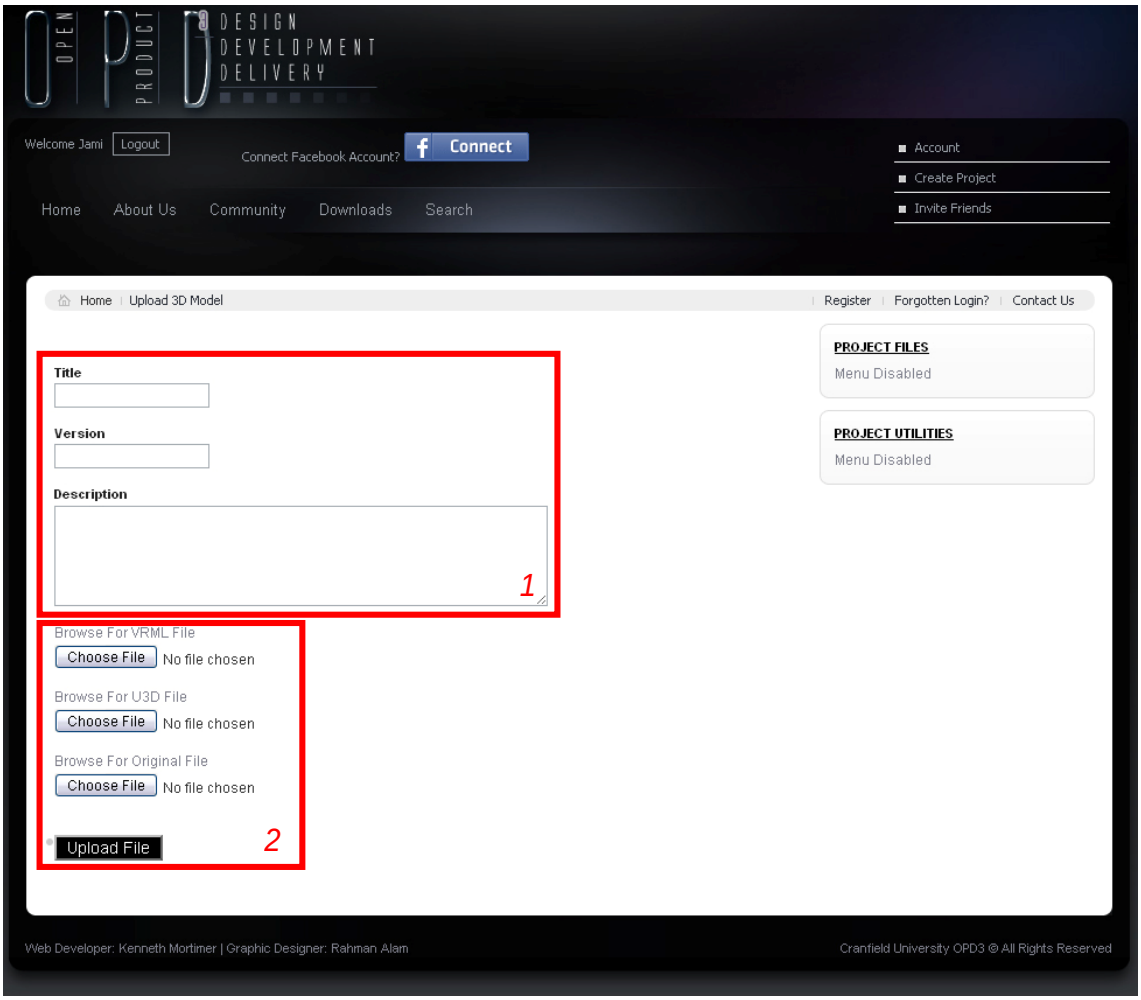


Figure 5-10: CAD model uploading page

1. Prior to upload, users are required to complete the form
2. Users must provide a U3D (*.*pdf), VRML (*.*wrl) and the original file alongside a 'CAD upload form' in a compressed file.

5.10. Virtual Arena

Figure 5-11: Virtual arena page

1. The Virtual Arena is the centre piece of the page, all uploaded images are displayed. The flash viewer is interactive and allows users to pan and zoom through the concepts.
2. By clicking the rotate icon on the right side of the images will display the details of image, as seen in the above figure 5.11.
3. Users can download the selected concept for further modifications if need be.

5.11. CAD Model Visualisation and Management Portal

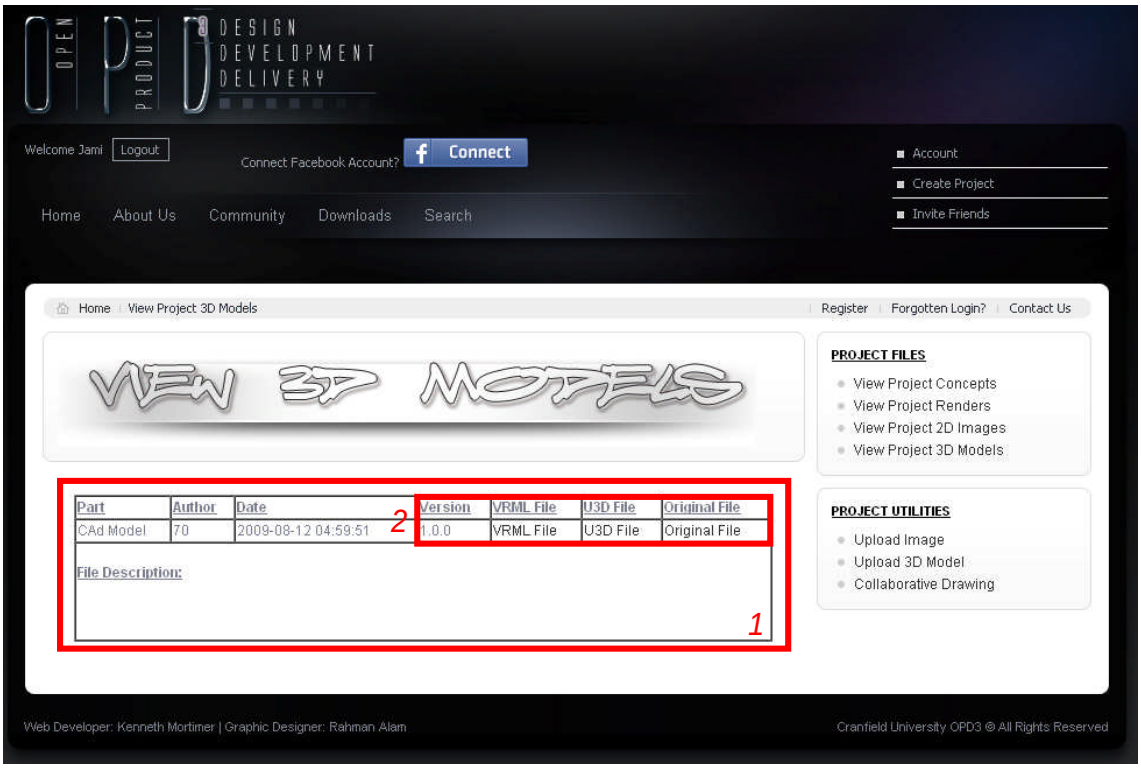


Figure 5-12: CAD model visualisation page

1. The content management table is developed which houses all the required CAD contents. Details of the part/assembly, with its corresponding version are shown to give the viewer the required information about the upload.
2. Participants can easily download the preferred CAD file by selecting the desired link.

To ensure full functionality of the sites, plug-ins must be installed on the system on which the site is being viewed on. A downloads page has been created which provides users with direct links to external sites from which the users can freely download the required plug-ins. The required plug-in includes:

⇒ Adobe Acrobat reader for viewing U3D files, Cortona 3D for VRML files *(within the browser)* and Adobe Flash viewer for viewing the interactive virtual arena

5.12. Summary

The chapter recorded the specifications of the system through the development of UML use case and sequence/activity diagrams. An organised framework and script for the concept creation process was put forth. Screenshots of the implementation and identification of key features was recorded. The continuing chapter will detail a live user trial that will be performed on the system.

6. IMPLEMENTATION AND DISCUSSION: LIVE USER TRIAL

To ensure all round compliancy of the developed framework it was essential to perform a live user trial. By doing so sufficient explanations and possible insights in to further development could be extracted through feedback from participants. This chapter records the details of the live user trial; initiating with the intent and strategy, followed by details of the favoured project. Furthermore the chapter details the design of semi structures questionnaire that was used to capture participants' experience. The chapter ceases with a discussion of the results of the live user trail.

6.1. Good Practice Guide

Before executing a live user trial a '*good practice guide for concept creation* in the OPD3 Medical Initiative' framework was developed. A PDF format was provided online for download, all participants were encouraged to read it and utilise it throughout the developmental stages of the projects. It contains all the required information for a beginner to navigate and get familiar with the site as well as successfully follow through all the stages of the concept creation process. The good practice guide is available in Appendix C.

6.2. Live User Trial

Provided is a description of the intent followed by a logical and strategic strategy to perform the user trial would ensure a high level of manageability is achieved. Due to the restricted time frame it was essential to utilise time effectively to perform all the necessary actions to gain the required results for analysis.

Intent: 'to initiate projects in all three categories and to put forth possible project proposals.' Participants will be asked to select from any of the projects, based on personal preference and part take in the project developmental stages, focusing closely on concept ideation and concept development.

Strategy: With the given time frame and resources to meet the required targets of the user trial seven activities were organised as a part of a strategy, see figure 6.1.

⇒ Launch: a project for each category will be launched; High risk category will host a project for a *needle free dispenser.* The medium risk category will host *a cardiac monitoring device* and the low risk project will look at *developing a domestic breast cancer monitoring test kit.*

⇒ Invitation for participation: external individuals will be sent a formal invitation as a request for participation using chain emails, word of mouth and using the Facebook connect feature.

⇒ Communicating project details: An initial briefing of the project will be given to the participants via the comments feature. These initial comments will be recorded and readily available for viewing by new participants.

⇒ Project feasibility: once a core team of *dedicated* participants has been developed, the feasibility and future prospects of the project will be discussed.

⇒ Arrange design team: Concept creation requires skilled individuals; a design and review team will be arranged though no participant will be pressurised.

⇒ Develop concepts: The design team will generate detailed concepts which will be made available to view in the virtual arena.

⇒ CAD models: 3D models, 2D drawings, renders and any other graphical publications that might be useful to the project will be developed an uploaded.

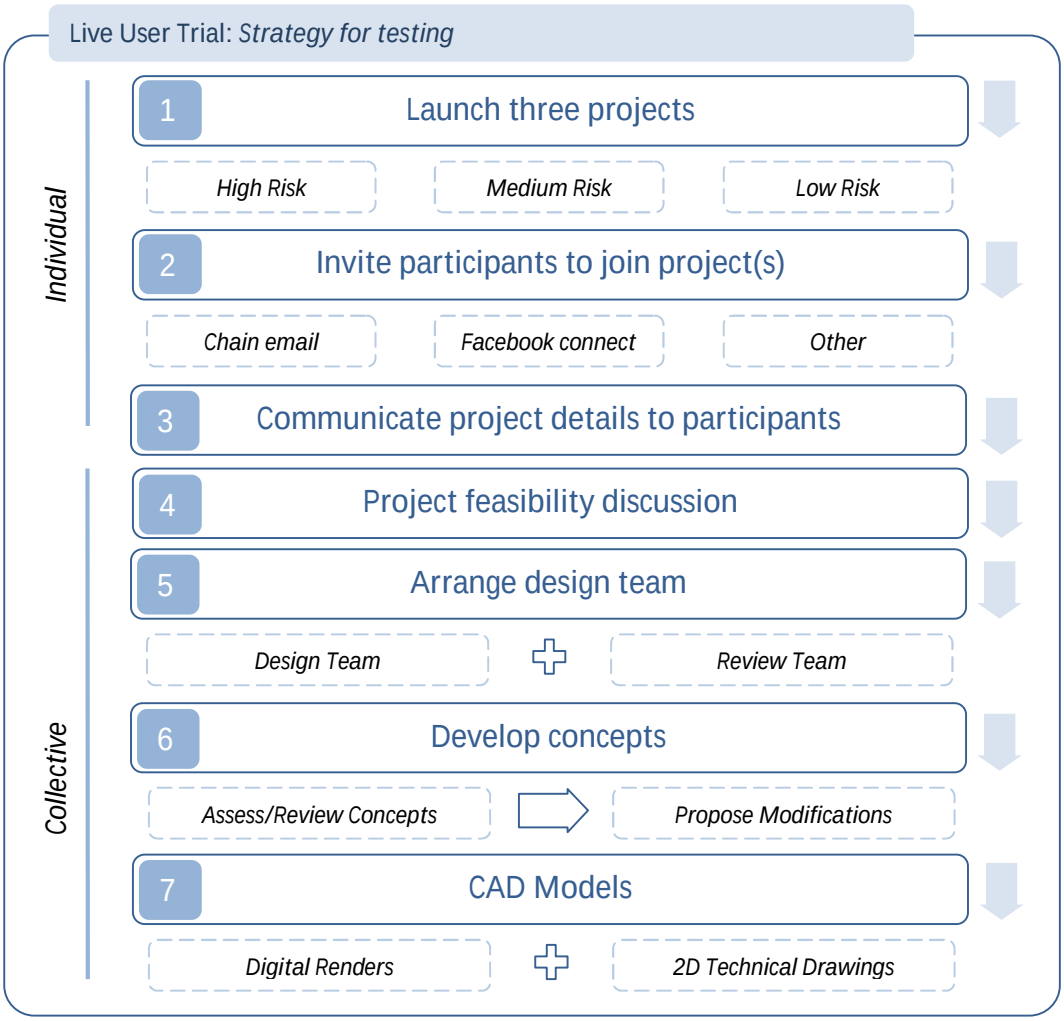


Figure 6-1: Strategy for testing

6.3. Details of Participants

Details of the participants have been organised and presented, the name, age, years of experience and the areas of contribution is included. The purpose of this is map details of the participants to visualise the diversity of skills and experience that was bought together as a result of this case study.

Name	Age	OPD^3 User Name	Background	Years of experience	Technical Role	Project Participation	Contribution
Steven Doyle	19	Steve_d	Student	n/a	Designer	M-risk	Concepts
Suresh Heer	23	Heer_123	Sales	5+	Design	M-risk	Ideas
Dr Metha	65	Dr.Metha	GP	35+	Admin	M-risk	Discussion
Abdul Alam	16	a.alam	Student	n/a	Design	M-risk	Concepts
Stacey Mendez	24	S_Mendez	Design consultant	4	Design	M-risk	Concepts/ discussion
Richard Haze	29	Richiee102	Graphics Designer	12	Design	M-risk	Concepts/ discussion
Jane Bourne	42	Jane_b	Design Tech Teacher	20+	Design	M-risk	Discussion
Richard Ambrose	20	Amby222	Student	n/a	Design	M-risk	Concepts/ discussion
Steven Jenkins	35	Jenk54	Graphics Designer	17	Design	M-risk	Concepts
Sopphia Khan	22	Sophie007	Student	n/a	Assistant	M-risk	Discussion

Table 6-1: details of participants

The details of the participants have been listed and it can be seen a wide range of skills, experience is bought to attention. The levels of contribution ranged from person to person however there was involvement from all participants in other areas of the case study. The next section will detail the case studies in more detail.

6.4. Live User Trial

This section details the live user trial that was performed, screenshots and annotations have been provided based on the 'test strategy' discussed in the previous section.

6.4.1. Launch

Three projects were launched, one for each of the categories. A self-administrating cancer testing unit for a low risk project, a cardiac monitoring and alerting device for a medium risk and needle free connector device for a high risk project.

Descriptions of the projects:

Low risk project

The low risk project of a self-administrating cancer testing unit was based on the research being carried out in Cranfield University. The specification of the project alongside its accompanying details was hosted on the site for viewers to review. The goal of the project was to develop concepts of a portable peripheral that could be used instinctively to make a self-assessment.

Medium risk project

The second project was based on designing and developing a cardiac monitoring and alerting device that could be used to detect heart attacks in patients that suffer from sleep apnea. Patients that suffer from Sleep apnea who have myocardial infraction and most likely to encounter heart attacks during sleep, therefore the design of the device should allow constant monitor of the patient and alerts to be made when the health of the patient decays which could potentially lead to a heart attack.

High risk

The final project was based on needle free connectors. Intra muscular and vascular administration of medication to patients requires needle connectors, which pose many health and safety concerns for both the patient and the nurses that administer. Therefore the development of a needle free connector could cut the risks of accidents and any health and safety risks that are posed with needle injectors.

The discussion of the three projects has been presented. Figure 6.2 displays a screenshot of the three projects being displayed on the homepage, allowing users to read the brief description and before joining the project.

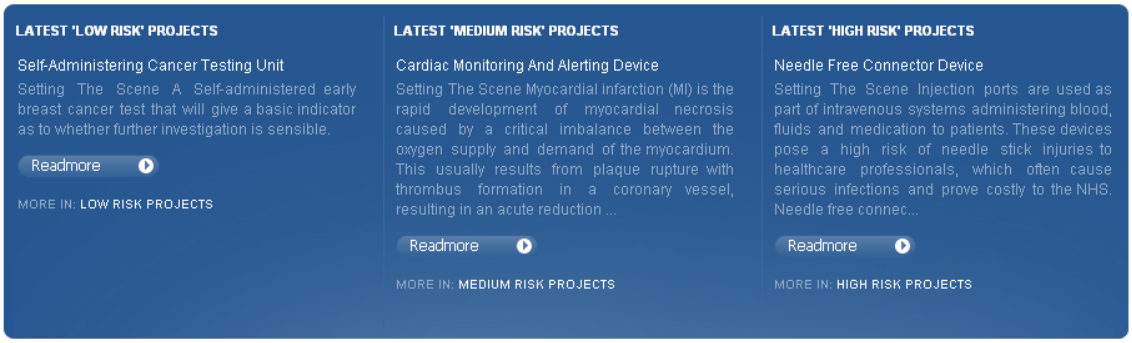


Figure 6-2: Details of the three launched projects

6.4.2. Invitation for Participation

Users were invited using the Facebook connect function on the site also traditional method such as word of mouth and emails were used.

Figure 6-3: Facebook connect feature

6.4.3. Communicating Project Details

The project details were published for all the participants to view and assess on the official project page as seen in figure 6.4.

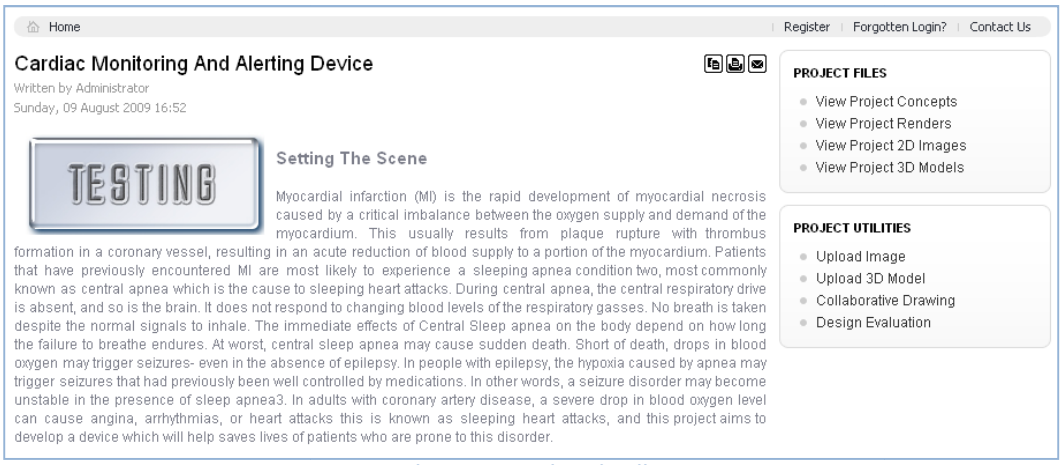


Figure 6-4: Project details

6.4.4. Project Feasibility

Once the core team of committed participants had been established, discussions on the feasibility of the project were on top of the agenda. Users started to post comments regarding the project and ways in which it could be made possible. Examples include comments made by Steve D (see figure 6.5) display a high level of enthusiasm and commitment followed by a logically sound argument. Stacey M continued by emphasising the importance of time and suggested that we needed to seek specialist advice before progressing any further.

Figure 6-5: Project feasibility discussion

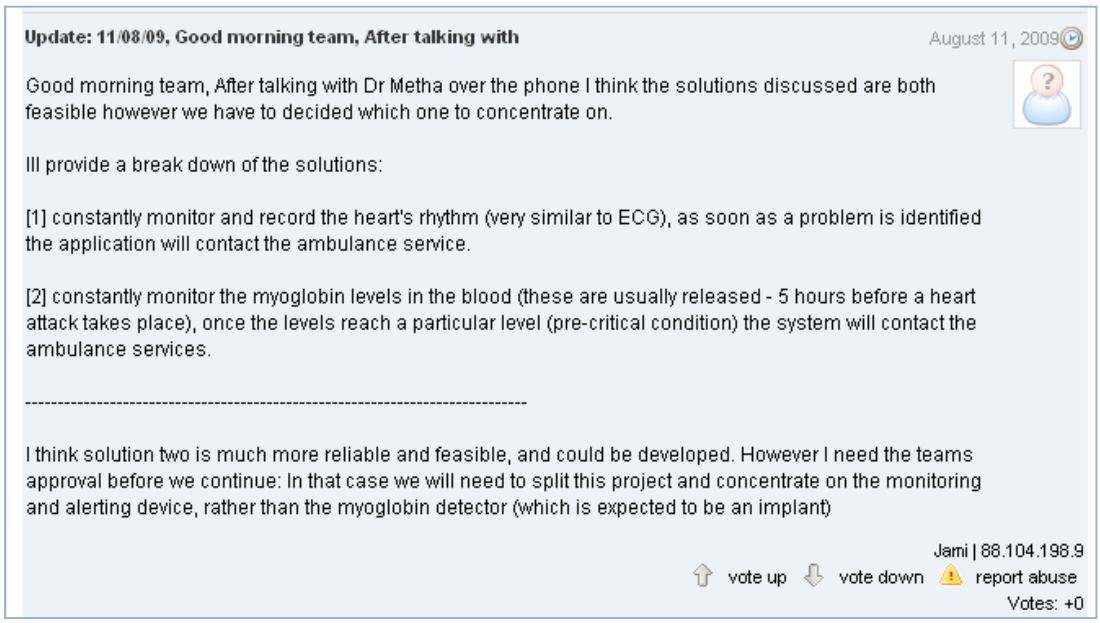


Figure 6-6: Seeking specialist advice

The discussion on feasibility continued following the consultation of a senior General Practitioner. Figure 6.6 highlights two feasible solutions that were the result of an insightful conversation with Dr Metha, who later on joined the project.

6.4.5. Arrange Design Team

A notice was sent to all participants of the project to construct a design team, this was a voluntary activity and therefore no one pressurized. Four individuals who had a strong background in design and engineering decided to form a team, the confirmation and arrangement of the team can be viewed in figure 6.7.

Figure 6-7: Design team confirmation

6.4.6. Develop Concepts via website

The website provided downloadable software such as Gimp and illustrator which users could use freely to generate concepts, however they could alternatively use the Flasitool to sketch online. The Flashitool allows users to upload either scanned or photographed images and edit them using the interactive functions. Most of the users reported to have considered using the software provided, however they also considered using their own software – in most cases Adobe Photoshop and Corel Draw.

Some users reported they scanned images in to the Flashitool and were able to directly edit the image using the interactive tools provided. They were then able to save and publish the files allowing users to comment on them. However they felt the quality of the images was poor and in order to publish the final pieces on to the arena they were required to use screenshot capture plugin and then convert the file in to an image format prior to uploading the image. Though once it was uploaded they were able to use the text and line tool to render the graphics accordingly.

The design team was able to generate a total of 14 fully detailed concepts within a matter of days. Correspondingly, the review team was able to access the virtual arena and visualise the uploaded concepts. Examples of reviews made by the review team can be seen in figure 6.8.

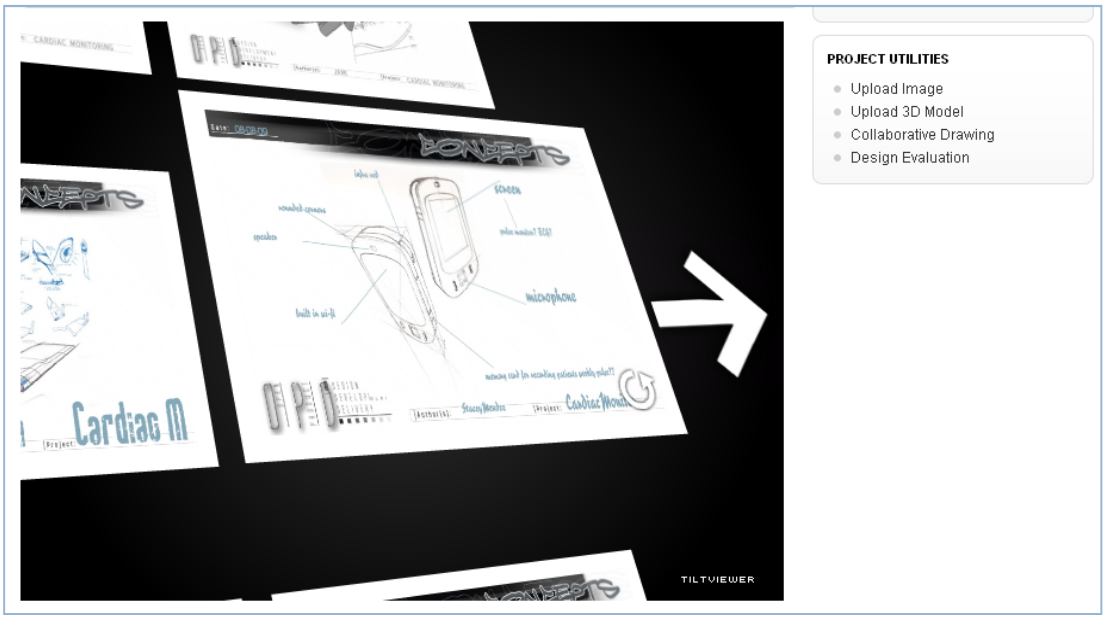


Figure 6-8: Virtual arena showing concepts

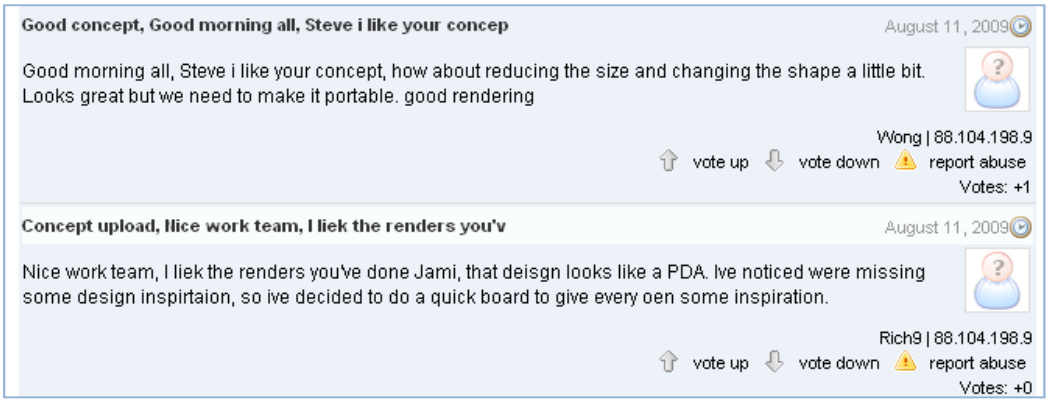


Figure 6-9: Design review comments

6.4.7. CAD Models

After uploading CAD files users left messages to inform the team members of the action. Posting messages as such is an encouraging and motivating factor that keeps teams members closely attached to the project.

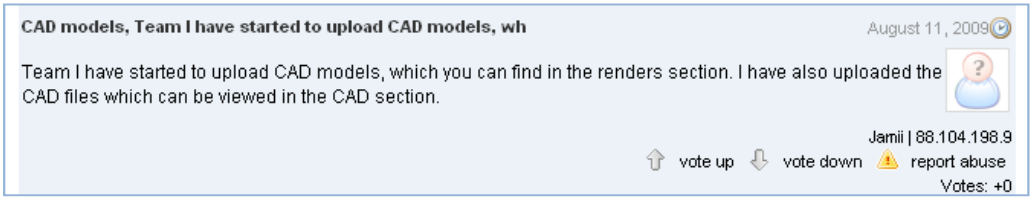


Figure 6-10: CAD upload message

Figure 6.11 displays photorealistic renders of CAD models that have been uploaded by users. A total of 15 high quality renders of the selected CAD had been produced and uploaded.

Figure 6-11: Examples of CAD renders

The commitment shown by the design team was over whelming. Users worked together to produce additional graphical publications such as the user guide for the selected concept as seen in figure 6.12.

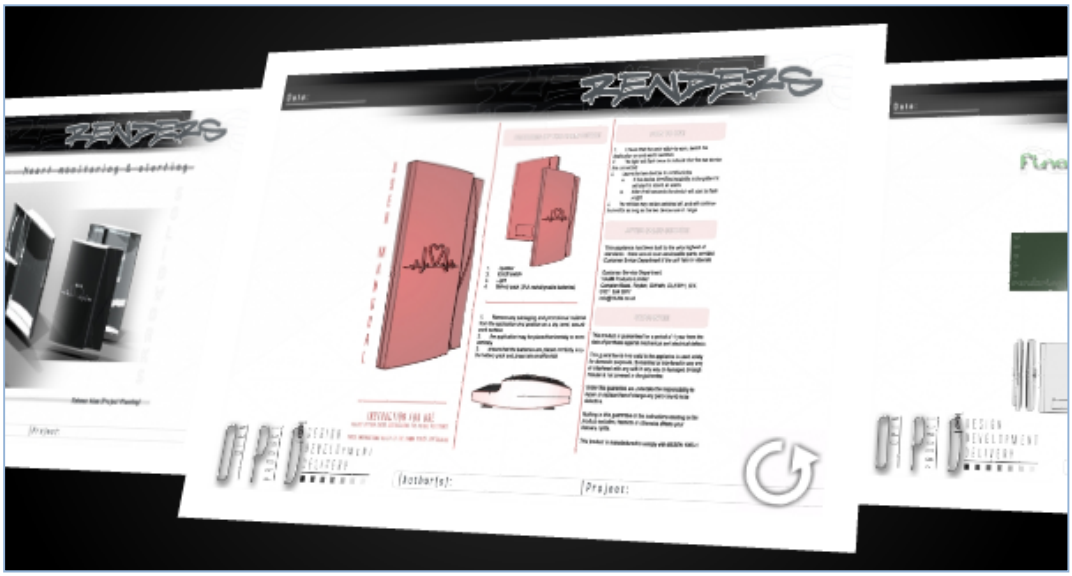


Figure 6-12: Additional graphical publications

The CAD portal was used to upload 3D contents for visual, review and modification purposes. Figure 6.13 delineates a table generated with the uploaded contents, participants could view VRML, and U3D filed within their browsers. Should they

require the original files for modification of the parts they could easily download it from the link provided.

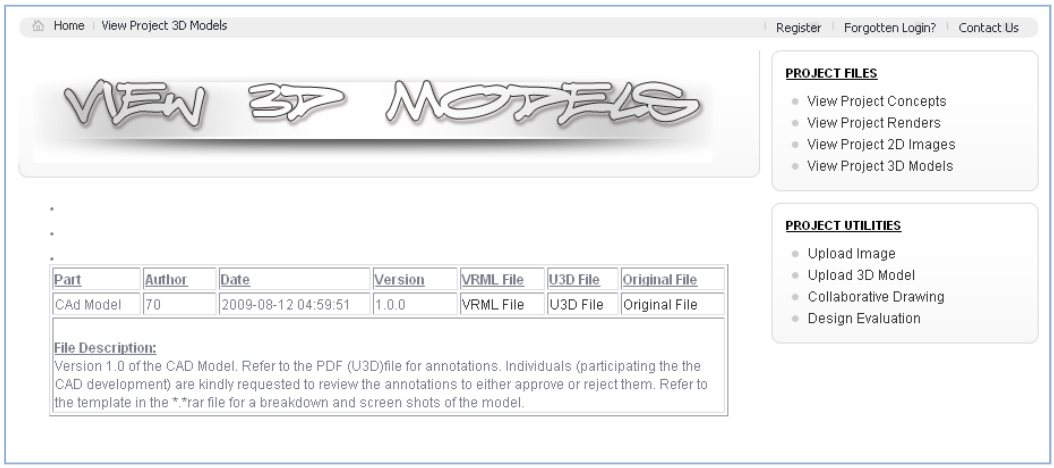


Figure 6-13: CAD portal

Figure 6.14 shows the VRML file opened in internet explorer using the Cortona3D plug-in. One can interact with the model to pan, zoom, rotate etc. with the model.

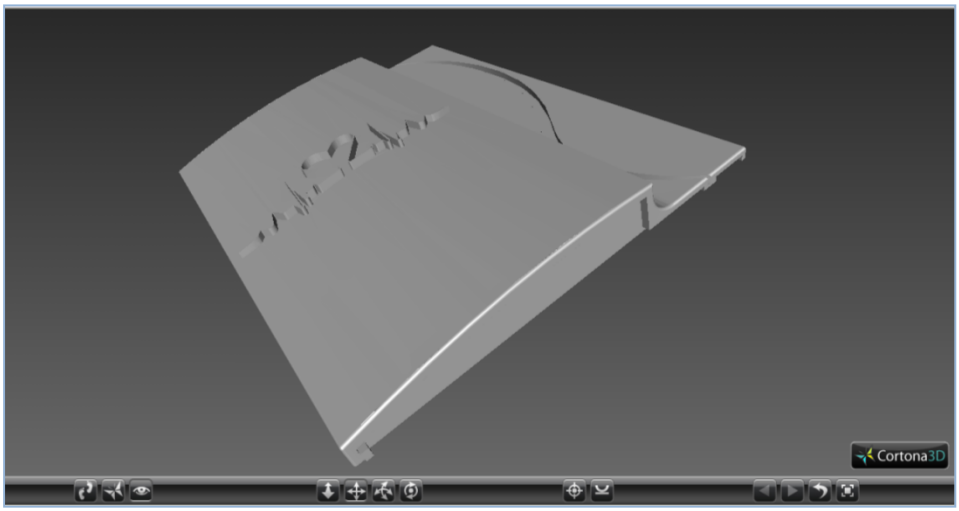


Figure 6-14: VRML filed opened in Cortona3D viewer

U3D is an embedded content feature of PDF files which allows them to be opened in Adobe Acrobat Reader. Figure 6.15 shows the CAD file opened in Adobe with its part tree fully accessible by the user. The PDF file is fully interactive; users can adjust the lightings, review annotations but also apply the measuring feature to calculate dimensions.

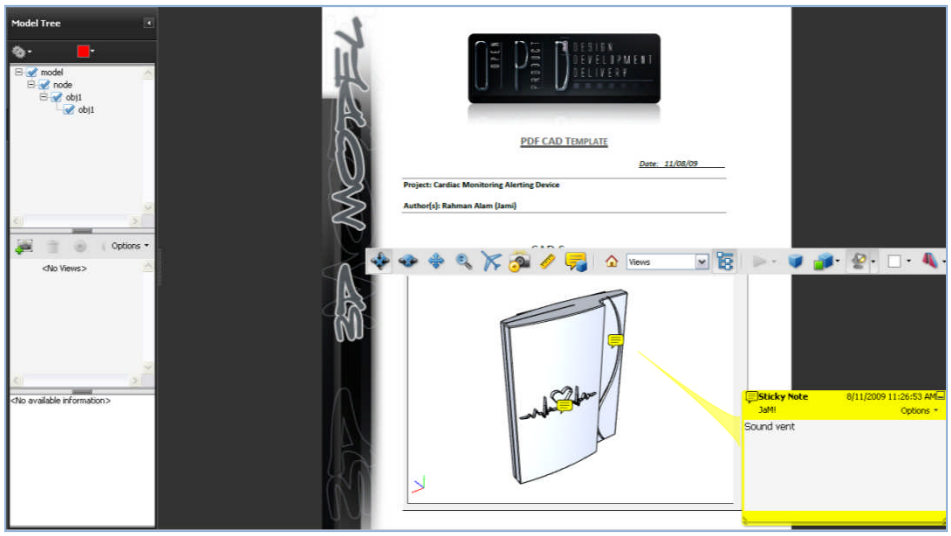


Figure 6-15: U3D file opened in Adobe Acrobat Reader

6.4.8. Limitations and Constraints

During the live user trial a number of limitations of the framework and its associated elements were noticed, details are been listed below:

⇒ *Inviting participants:*

Over one hundred invitations were sent requesting individuals to participate in the projects of which only 15 individuals participated. Convincing and motivating users was very difficult.

⇒ *Concept creation:*

Majority of the users used the provided software for the development of graphical illustrations however learning a new software required additional time. In this case it was noticed though they considered using the software they felt they were comfortable using their preferred software which they more comfortable using.

Additionally the Flasitool provided a new way to interactively develop graphical illustrations online without the worry of installing and licensing software. However users felt the tool did not provide the more powerful features such as blend between layers. Many users felt by scanning images in to Flashitool caused a distortion to the image, which meant they could not preserve full quality. Due to this they were forced to revert to their previous software.

The limitations with the concept creation process have been identified however considering it is a step forward in providing a platform with all the necessary tools to generate concepts gives way to people of all ages to collectively design and develop. In order to further develop this, it is believed more reliable graphics

software is to be provided with additional documentation which should allow users to learn the software without difficulty.

⇒ *Technical Experts:*

Doctors, nurses and other medical professionals were contacted via email requesting participation. Unfortunately the response was minimal, with the busy working lifestyles some turned down the offer. Participation of medical professionals in an environment as such requires a great deal of contribution and administration as they possess technical knowledge. In the case of the cardiac project a family friend of the author who is a General Practitioner was repeatedly asked to part take who eventually registered but the contributions were minimal.

⇒ *Facebook connect:*

One of the main inviting tools was Facebook connect; on numerous occasions the site serve was unable to synchronise with Facebook as there were technical faults.

⇒ *Project Focus:*

Keeping users focused and intact with the project was a major issue; some users were not so serious about the projects. Occasionally the responses received from some participants were off track and had nothing to do with the project. An aspect of social communal development was witnessed, which can in fact have a major effect on the progression of the projects.

6.4.9. Summary

The chapter has detailed the creation of the live session; details of the three projects on the site were detailed. Screenshots of the case studies were presented and the complete process was thoroughly discussed, the overall progress made was phenomenal and beyond expectations. The participation and commitment shown by users was the reason why the project was able to progress at such a successive pace. The proceeding section will give an insight in to the development of the questionnaire that was used as an assessment tool, followed by a discussion of the results.

7. VALIDATION OF FRAMEWORK

To assess the outcome of the live user trial, providing a personal account followed by an assessment of the final result against the predicted outcome would be insufficient. Participants varied in age, background, profession and every participant contributed differently from one another. Capturing their views would provide an insightful explanation of their experiences. A semi structured questionnaire was developed with the intent to capture their overall experience through the project progression. This chapter details the design of the questionnaire followed by a discussion of the results.

7.1.1. Questionnaire construction

The questionnaire begins with a brief introduction followed by the objectives. Users are asked to complete a section about themselves which includes, name (OPD[3] registered user name), age, background, years of experience and areas of contribution in the project. Preceding this, users are asked to complete a total of seven sections of the questionnaire, which look in to seven particular areas.

7.1.2. Sections and Key questions

Explanations of the seven sections and key questions posed in the section are discussed; see Appendix D for an example of the questionnaire.

Section 1: *Site awareness/participation*
This section aims to gather general information of how the participant was introduced to initiative and what role they took upon registration.
Key questions include: [1] did you registers a valid user? [2] Did you initiate a project/ request participation/ received invitation?

Section 2: *Structure of Design Arena*
Navigating throughout the design arena should be easily conformed to allow beginners to easily get familiar with the features and tools available. This section tries to capture what the users felt about the structure of the design arena.
Key questions include: [1] were you able to navigate throughout the *Design Arena* without difficulty? [2] Were you able to find the required information *Design Arena*?

Section 3: *Ideation Section*
Ideation serves as a vital function in the developmental stages of the project. Users must participate regularly to keep to date with latest maturations. Questions have been asked regarding involvement in the process and possible ways to improve it.
Key questions include: [1] how often did you refer to the *ideation comments section* during the project? [2] What changes would you like to see in the Ideation section?

Section 4: *Concept Creation Toolbox and Techniques*

Tools and technologies have been made available to users freely to aid in the concept creation process. Questions have been asked to see to what extent did the users utilise these.

Key questions include: [1] Were you able to create, save and upload concepts in to the arena without any difficulty? [2] Did you consider using the open-source graphics applications provided in the download section?

Section 5: *CAD Data Collaboration*

The process of CAD modelling requires a team effort to successfully reach a solution. This section has been designed to ask participants if they were able to collaborate with other teams members for CAD development.

Key questions asked: [1] Did you contribute to an original CAD file uploaded by another team member? [2] Did you work with along side another registered team member to develop CAD models at any stage of the project?

Section 6: *Collaborative Design*

Collaborative design is the essence of the OPD3 medical initiative, the structure of the framework has been designed to ensure this is achieved. Participants have been asked question in relation to this.

Key questions asked: [1] Where there sufficient tools and techniques provided to collaborate with fellow designers? [2] At what stage of the project did you utilise resources with a fellow participant of the project?

Section 7: *Design Contribution and Licensing*

The OPD3 Medical initiative is based on open source concepts, it adheres to the creative commons license. Capturing peers view on sharing ideas/concepts for open source design is necessary to determine how serious they were about participation. Such questions have been posed to capture participant's views on licensing and sharing knowledge.

Key questions asked: [1] OPD^3 operates using the open source creative commons license; did you hesitate at any stage in making contributions? [2] How do you feel about sharing ideas and designs in a team to develop medical products?

The section has detailed the creation process from the live user trial based on the strategy for testing. Screenshots and explanations have been presented to show all the aspects of concept creation. Construction of a semi structured questionnaire has been recorded. The following section will record and delineate results received from the questionnaire completion.

7.2. Live User Trial: Results and discussion

Following the live user trial covered in previous section, users were asked to complete a 'user experience' questionnaire which was developed in chapter 7.4. The results collated from the completed questionnaires have been covered in this chapter. The results have been graphically and statistically displayed, followed by a discussion.

7.2.1. Participants information

This section provides an analysis of peer information; general aspects i.e. age group, gender etc. to gain an understanding of the participants.

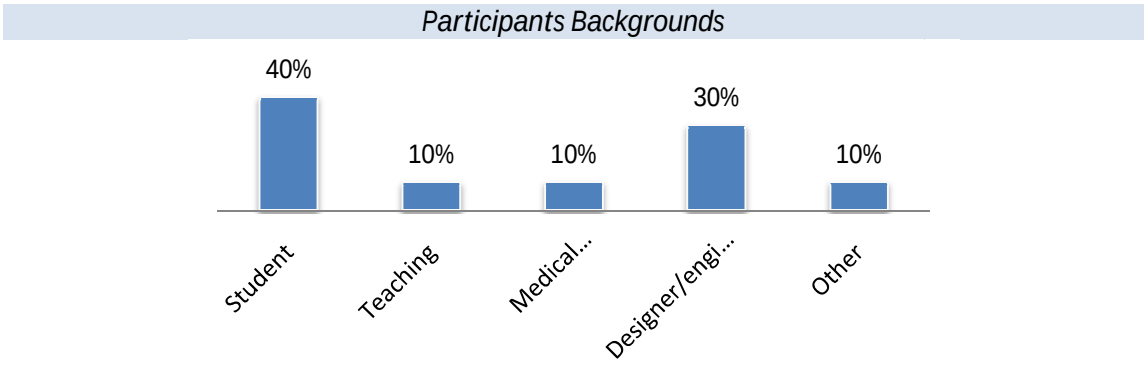


Figure 7-1: Graph to show participants backgrounds

Discussion: the results above indicate a variety of backgrounds of the participants, though majority of them were students. Participation from individuals from the health sector as well as design/ engineering provides was also witnessed.

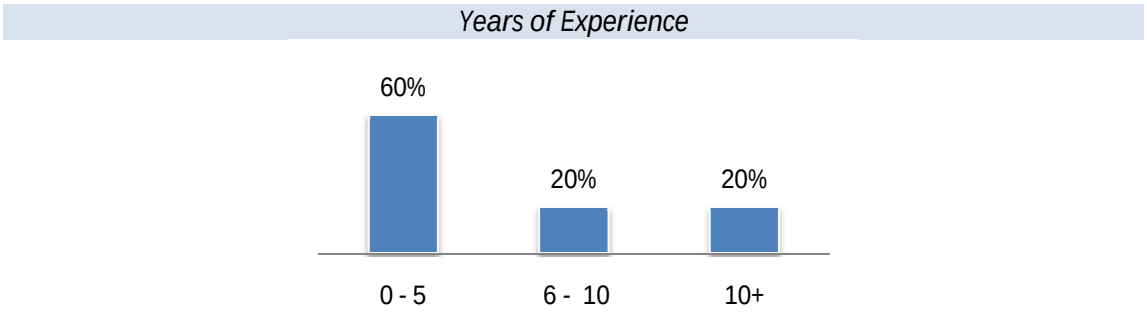


Figure 7-2: Participants years of experience

Discussion: Majority of the participants were novice however more senior and experienced individuals also took part. It's clear that the system can accommodate users with all levels of experience.

Gender

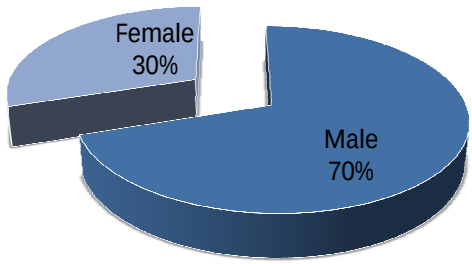


Figure 7-3: Gender of Participants

Discussion: contribution from both genders was seen in the project.

Age Groups

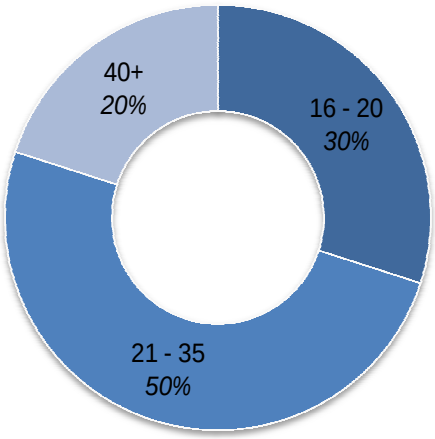


Figure 7-4: Age group of users

Discussion: From these results it has been identified that a balanced age group was established. Half of the contributors were mature individuals, however senior and young adults also contributed.

7.2.2. Section 1: overview

The results from this section elicit that a culture of social variation has been established which has been easily accommodated within the OPD^3 medical initiative.

7.2.3. Site awareness and participation

Capturing an understanding of how users came to know about the initiative and through what methods is important.

1. How did you find out about the OPD3 Medical initiative?

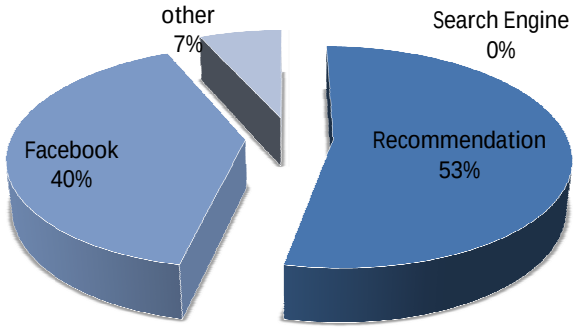


Figure 7-5: Informative methods for participation

Discussion: the rapid growth of the network can only be explained through recommendation. It is clear that upon registration users recommended the site to close friends, family and co-workers. Facebook connect tool was shown to be very useful and very practical in inviting new comers to the project.

2. Did you register as a valid user?

Yes	100%
No	0%

Discussion: results confirm that all of the participants successfully registered.

3. Did you initiate a project/ request participation/ received invitation?

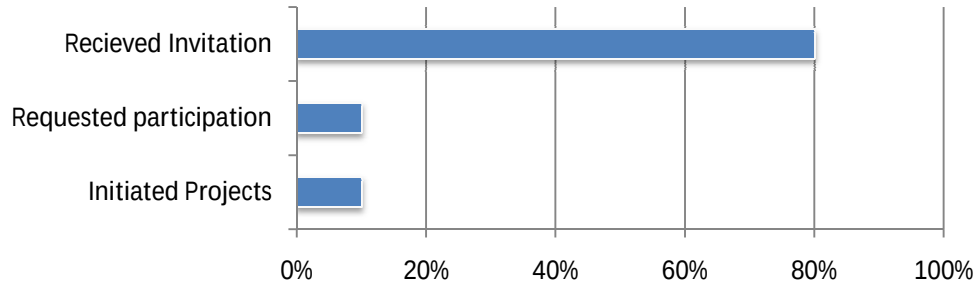


Figure 7-6: Project position taken up by registered users

Discussion: These results confirm 80% of the participants received invitations. By inviting others to the initiative is a very good way of opening the doors.

4. Upon registration did you invite others to the project, if so by what methods?

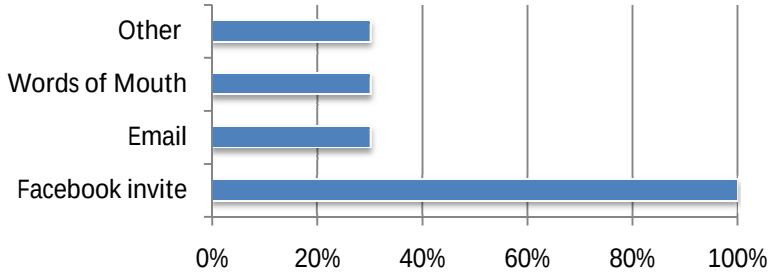


Figure 7-7: Methods employed to invite new members

Discussion: all the registered users invited new members; the most popular method used was Facebook. Traditional methods were also employed, though they didn't seem to be as popular as Facebook connect.

7.2.4. Section 2: Overview

The section has recorded some very useful facts about the participants; all invited users registered and utilised the available tools to invite others. It's apparent that recommendation is the biggest tool in inviting new users to the site, and Facebook connect helps.

7.2.5. Structure of the Design Arena

This section concentrates on the structural impact of the design arena and records user's responses about the current layout and ways enhance it further.

5. Were you able to navigate throughout the Design Arena without difficulty?

Yes	100%
No	0%

Discussion: A simple yet coherent theme was designed to ensure users could easily navigate through the design arena. All the participants exclaimed that they were able to do so without difficulty.

6. What do you think of the structure of the Design Arena?

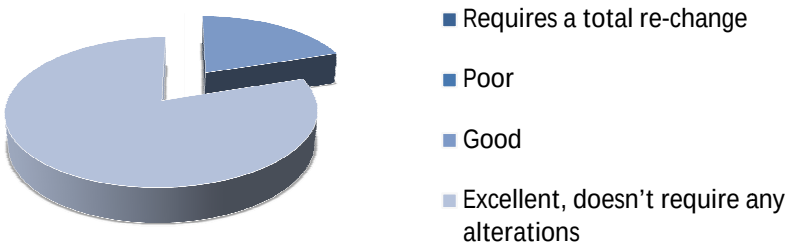


Figure 7-8: Structure of the Design Arena

Discussion: The structure of design studio has been developed to allow participants to access all the necessary tools required to progress through all the developmental stages. 80% of the participants claimed that the structure of the site was excellent and didn't require any further alterations. While 20% believed the arena was satisfactory.

7. Were you able to find the required information in the Design Arena?

Yes, I was able to found information I was looking for	80%
Yes, but only in some sections	20%
Fairly	0%
No, the layout is too complicated	0%

Discussion: having access to the right information at the right time during concept development is vital. The results indicate that the users were able to successfully find the required information.

8. What do you think of the theme of the *Design Arena*?

Very good	90%
Good	10%
Poor	0%
Very poor	0%

Discussion: the response received with regards to the theme of the design arena was positive.

7.2.6. Section 3: Overview

The questions within this section try to capture the participants view on the design arena; general questions with regards to the structure, theme etc was asked. The results were positive which therefore means the design arena is suited to serve its purpose and shouldn't require any further modifications.

7.2.7. Ideation section

The ideation section serves as the principle discussion point which is used by the core team to develop the technical specification, from which the design specification is developed.

9. Did you participate in the ideation discussion at any stage of the project?

Yes	80%
No	20%

Discussion: participation in the ideation session provides users with individualistic understanding of the decisions for the project. The results show that 80% of participated during the session, the remainder 20% were unable to different timings.

10. How often did you refer to the ideation comments section during the project?

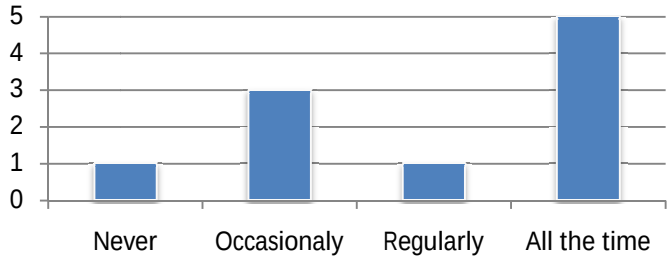


Figure 7-9: Ideation participation

Discussion: there is a variation of participation in the ideation process, 5 participants referred to the ideation 'all the time' (the core project team), the remaining used the ideation as a referencing point.

11. Advantages and disadvantages of the Ideation section as listed by participants

Discussion: Users were asked to list 2 advantages and disadvantages they found in the ideation section.

Common advantages listed were: (1) records of the discussion and final decisions made are archived and available for viewing at any time. (2) It is sustainable and cheaper to use the ideation process than to meet up and host a meeting. (3) Opportunity to develop as a cyber-network and allow geographically dispersed individuals to join freely.

Commonly mentioned disadvantages included: (1) there can be an overload of information and staying on track can be difficult. (2) No method of managing the uploaded contents i.e. deleting useless comments and organising decisions in to sections is unavailable.
From the results it is made obvious the ideation section has strengths and weakness, with a better management system the experience would be improved greatly.

12. Did you find the RSS feeds function useful?

Yes	70%
No	30%

Discussion: RSS feeds (Rich Site Summary) were incorporated in to the ideation section to allow users to keep up to date with the latest discussions on their handheld PDA's or smart phones (Blackberry, iPhone etc.). A high number of participants found the RSS feeds function useful as they were able to keep up to date with the latest updates.

13. Desired developmental changes in the Ideation Section

Discussion: as a method of ensuring on-going development to the site, this question was asked to find out what changes the participants would like to see as an improvement. The biggest concern users had was firstly content organising management and secondly ensuring participants strictly stay on track. Both points indicated by the participants are important, the first can be achieved by allowing users to section out contents and manage it categorically. The latter will not be discouraged because through social interactions users build and gain trust which plays a great role in project development.

7.2.8. Section 4: Overview

The results gained from this section have been very useful, it has been identified that there is still room for further improvement. Participants have shown concern in the way the content in the ideation section is managed. By organising the discussions will save a great deal of time in locating information when required but also it will ensure system coherency.

7.2.9. Concept Creation: Tool and Technologies

To provide users with a rich experience during concept creation, a toolbox was developed in which latest software technologies were integrated. These were freely available for the registered users to utilise during concept creation. This section solely focuses on revealing users responses with regards to the *Concept Creation* toolbox and the technologies within it.

14. Did you consider using the open-source graphics applications provided in the download section?

Yes	80%
No	20%

Discussion: carefully selected open source applications were provided for users for graphics and CAD creation. Results indicate that 80% of the participants used/considered using the applications provided. The remaining 20% didn't consider using the OS applications; they chose to use commercial applications.

15. Did you use any other graphic application(s) other than the ones provided on the sire, if so which ones(s)?

Yes	20%
No	80%

Discussion: in addition to the OS applications provided the commonly used commercial package were Adobe Photoshop and Corel Draw. However the OS applications provided are rated up to the standards of these commercial packages.

16. Did you use the flashitool for online sketching and annotation of designs?

Yes	56%
No	44%

Discussion: an interactive flashitool was incorporated in to the virtual arena, giving user the ability to collaboratively produce digital concepts. Results confirm that 56% of the users of which 100% were students utilised this tool fully.

17. Did you take advantage of the mind-mapping application during the brainstorming sessions?

Yes	34%
No	66%

Discussion: mind mapping is a way of visually representing ideas; most designers revert to this method to extrapolate diverse ideas. An OS mind mapping application was provided; statistics show that 34% of the participants used it (which is 100% of the design team).

18. Did you consider using the templates provided to display concepts, renders and 2D drawings?

Yes	88%
No	12%

Discussion: The use of templates has been made obligatory, 12% of users that didn't use the templates didn't participate in the upload of design contents.

19. Do you believe the method used to manage designs is accurate and effective?

Yes	100%
No	0%

Discussion: participants had acknowledged the management system to be accurate and effective. No one reported any issues or misuse, which means it doesn't require any alterations.

20. Were you able to create, save and upload concepts in to the arena without any difficulty?

Yes	88%
No	12%

Discussion: the design team was able to upload deign contents on to the arena without difficulty; 12% indicated in the results is referring to participants that didn't take part in any design activities.

21. After uploading your design, were the files clearly displayed or did they become distorted?

Highly Distorted	0
Slight Distortion	0
No Distortion	100%

Discussion: preserving quality of digital data such as designs and renders is critical; statistics confirm that the virtual arena is able to maintain the quality to ensure no distortion takes place.

22. Do you believe the interactive flash banner portrays the concepts in an acceptable, elegant and correct manner?

Yes	100%
No	0%

Discussion: a flash based interactive banner is used to display designs, and the users confirm that it displays the contents in an elegant manner.

23. Would you prefer seeing the concepts, renders and 2d drawings sections separate or all displayed all together on one page in a single flash banner?

Single	100%
Together	0%

Discussion: currently three virtual screens are being used to display the contents singularly and users suggest this is the right way than to incorporate all three sections under one screen.

7.2.10. Section 5: Overview

The results recorded in this section have been very insightful; users have shown interest in adopting OS applications in the generation of digital contents. The response received with regards to the technologies being used to display the design contents was also positive.

7.2.11. CAD Data Collaboration

The OPD^3 framework was designed with the intent to accommodate motions for collaborative CAD development, the answers listed below specifically focus on this.

24. Do you think the layout of the CAD portal is suitable?

Yes	100%
No	0%

Discussion: users found the layout of the CAD portable suited to its purpose which meant users were able to upload, manage and collaborate without difficulty.

25. Which of the viewers listed did you have preinstalled?

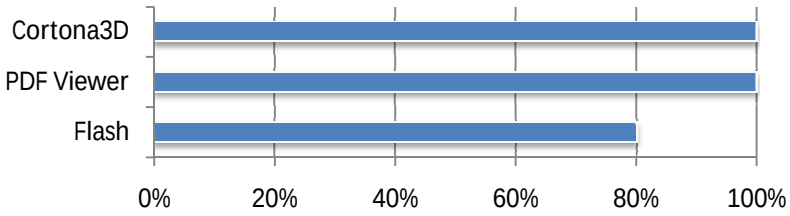


Figure 7-10: CAD model viewing plug-ins

Discussion: to view the CAD models users are required to install browser plug-ins, Cortonoa3D and Adobe Acrobat Reader. Flash is required to view the virtual arena. All the participants had pre-installed the required browser plug-ins to view the CAD files.

26. Which of the universal file format did you prefer for visualisation of the CAD file and why?

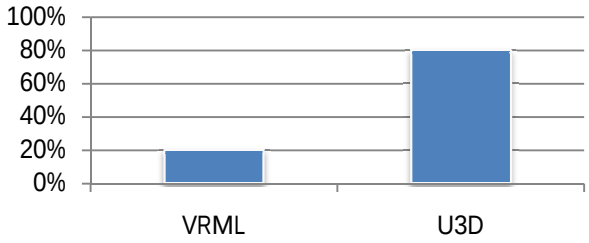


Figure 7-11: Preference for CAD visualisation plug-in

Discussion: users preferred U3D due to the incorporation of animations and the weighting of the file is very light. Some participants preferred VRML as they use it regular and via VRML they are able to directly produce prototypes using 3D printers. The strengths of both file formats is understood and therefore made available to the user.

27. Did you at any point annotate, modify and reload an existing U3D (PDF) CAD file during project development?

Yes	10%
No	90%

Discussion: PDF files have an advantage over VRML files as they are easily readable for reviewing and annotation. Users were able to modify and re-loaded edited U3D files to and from the system.

28. Did you work with alongside another registered team member to develop CAD models at any stage of the project?

Yes	90%
No	10%

Discussion: these results confirm that at some stage during concept creation users were collaborated with one another in developing either a part or an assembly.

7.2.12. Section 6: Overview

The process of developing CAD models is collective and calls upon teams of designers to come together to develop parts, which are then organised in to assemblies. Results from this section statistically prove that users have been able to successfully collaborate and develop CAD models during the project.

7.2.13. Collaborative Design

This section deals with the general aspect of the collaborative design method. It aims to identify areas in which users collaborated mostly and what methods can be employed to enhance the collaboration process.

29. Where there sufficient tools and techniques provided to collaborate with fellow designers?

Discussion: all the participants stated that there were sufficient tools and techniques provided to successfully collaborate throughout the designer process.

30. During what part of the project did you collaborate most with either an individual or a team?

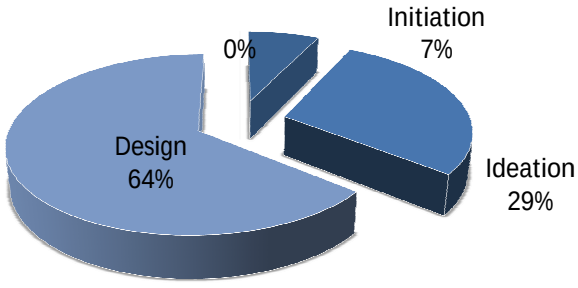


Figure 7-12: Details of collaboration

Discussion: the area in which most of the collaborative work took place was design. It is though necessary to mention all the areas are complimentary to one another. For instants the collaboration at the initiation stage made way for ideation, while the ideation stage led to the design phase.

31. How effective is the collaborative method provided by OPD^3?

Very effective	50%
Effective	50%
Somewhat	0%
Not effective	0%

Discussion: users believe the method of collaboration is between effective and very effective which is comprehensible.

32. Were you able to handle conflicts and solve design challenges without difficulty?

Yes	100%
No	0%

Discussion: conflicts usually arise between novice and senior designers in most projects. In this case conflicts were handled successfully to ensure a professional atmosphere was maintained.

33. At what stage of the project did you utilise resources with a fellow participant of the project?

Discussion: a user reported to have asked a fellow team member to add annotations to design prints and share a font. Other team members reported to have shared CAD skills and knowledge during the creation of parts. A culture of sharing and utilising one another's resources had been established and team members had gained trust and confidence to openly ask share and care.

7.2.14. Section 7: Overview

The corroborated results highlighted that conducing collaboration in the framework is possible, all three stages of concept creation showed activities of collaboration. Users exclaim that there were sufficient tools and technologies available to conduct collaborative design.

7.2.15. Design Contribution and Licensing

This section deals with legislative and social factors associated with the initiative, issues such as licensing and contribution of ideas are discussed.

34. OPD^3 operates using the open source creative commons license; did you hesitate at any stage in making contributions?

Discussion: this was the most important question in the questionnaire; the response received from the participants was overwhelming. Some of the responses include:
"Its all for good cause"
"We needed something like this in the community to act as one"
"Sharing is caring"
"Its good, we should encourage schools to participate in this process, to get youngsters involved at an early stage"

Not a single person was hesitant to participate in the initiative, registered users contributed greatly as a part of this.

35. How do you feel about sharing ideas and designs in a team to develop medical products?

Discussion: results made by comments with regards to the intent of the initiative have been noted:
"It's the way forward, this is revolutionary"
"Good idea and every one should take part in this"
"OPD is a challenge"
"I will become famous"

The reasons for participation can be seen as individualistic and collective, though in most cases it's for social welfare. The concept of the initiative has been understood and appreciated; with this attitude the future of OPD3 is bright.

36. Are the terms and conditions clearly listed and easy to follow?

Discussion: in accordance to the license of the creative commons law, terms and conditions were created; additionally exclusive regulatory aspects related to the site were listed. The terms and conditions were clearly listed and all the users were able establish a firm agreement without difficulty.

37. How committed are you in ensuring products are bought to the market?

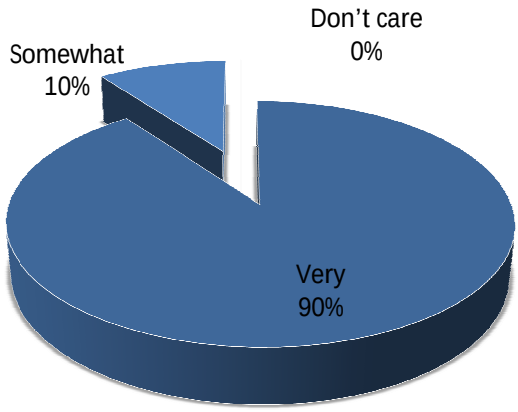


Figure 7-13: Project commitment

Discussion: the commitment shown during concept creation was positive, and it is obvious from the above results that the users are committed enough to go beyond the conceptual phase and ensure products are bought in to the market.

38. Which additional techniques, tools & technologies can be added to improve the future of the initiative?

Discussion: to further raise the standards of the initiative users were asked to list things that could be incorporated in to the current framework, some of the prominent suggestions included:

(1) Instant messaging (instead of discussions in the ideation section).
(2) Language translation to make the initiative available to non-English speakers.
(3) *Develop a desktop application version as well as the web-based and keep them both synchronised.*

Instant messaging could be used to allow users to make social conversations, while using the comments in the ideation section solely for project related conversations.

To further develop the site in to a global level providing the feature to translate is extremely important. This will allow users from east and west to come together and not encounter any difficulties in participating in the project.

Sufficient funds are not available to develop a desktop versions, however it is a great idea as it would make the system more personal to the users. Most firewalls prevent downloads and uploads of contents from internet sites, by providing a desktop version which is synchronised with the FTP folder will allow users to upload and download.

7.2.16. Licensing and Commitment

Users did not express any concerns with the licensing and terms and condition. Commitment to further participate in the complete development of medical products has also been shown. Participants have also put forth suggestions which will further enhance the initiative.

7.3. Summary

The chapter recorded the results from the live user trial discussed in opening sections of this chapter. The response was positive; participants expressed their views and put forth suggestions for further improvements. The proceeding chapter ceases the research with the conclusion.

8. CONCLUSION

The final chapter initiates by discussing the methodology that was developed and employed for the research. The results of the research including the difficulties encountered during the development of the framework are mentioned. A comparison of the live user test results against the expectations is noted. Furthermore, a conclusion to the research is recorded.

8.1. Quality of Implementation

The methodology used for this study consisted of three sections; familiarising, Investigating and conjecturing. The familiarising and investigating phases were all research based; theoretical mainly with an element of particle.

The research conducted through the literature review provided the platoon on which the project was constructed. Gaining an insight in to open source initiatives and collaborative and virtual product development provided sufficient knowledge and understanding to allow the study to mature further.

Through investigation it became apparent that there was not an open source platform that was being used for 'concept creation' of products. This provided an open-opportunity but also required the development of a generic concept creation model for medical device design and development.

A framework was proposed, the requiring elements for implementation were logically presented with the aid or activity diagrams and site scripts. Technologies, tool and techniques were proposed for each process. The practical aspect of the familiarisation phases required the physical development of graphics and contents that would be used to create the web framework.

Once the framework had been developed, the final stage of the methodology called upon the conjuncture of the findings which was to perform a live user trial. Based on a strategy the user trial was followed. Three projects; one for each category was proposed. External invites allowed individuals to participate in a project of their choice.

The complete concept creation process was followed for the medium risk project. The user's commitment, response and input were positive. A final solution had been achieved which was now at the next stage of development.

The construction and placement of activities within the methodology assured all the necessary requirements and targets were met. All the project objectives were successfully completed in a constructive and justifiable manner.

8.2. Discussion on Quality of Results

The findings from the research identified a clear need for a project that would address the issues of collaborative development using OS methodologies. A generic framework for concept creation of medical devices was not located, one however was developed. The intention of the framework was to ensure a continued and dynamic approach to concept creation could be made viable in a virtual environment.

Through thorough development and technology selection the framework was developed. The live user trial was sufficient in assuring that the framework was complete in the sense of knowledge sharing and product development. The progress of the research has witnessed a trend of successive paths.

Considering the user trial was the first attempt in exposing the virtual concept creation process to the public, it has to be exclaimed that the framework was able to perform its required functions. The user friendly environment in which it was implemented allowed users to follow all the required phases without difficulty. The positive results gained from the research are greatly due to the extraction and execution of the most effective methods from literature and personal knowledge.

8.3. Research Adaptation

The primary focus of this research was to design and develop a framework for implementation. The newly developed framework constitutes two major advantages, firstly it can be used for virtual creation and secondly it can be adapted to non-virtual environments.

Should one feel the need to develop non-medical devices and focus more on industrial products using the framework, they can by ignoring key stages of the process such as device categorisation.

The virtual arena can accommodate industrial and product design, purely because all the key design activities are similar to some degree.

8.4. Contribution to knowledge

The contributions to knowledge made by the author through this research is vast, specifically some contributions include:

- Identifying the potentials of OS in the development of product design.
- Incorporating OS within an online collaborative virtual environment.
- Design and development of the first concept creation process for medical device development in a virtual environment.
- System requirements and activities for virtual concept creation
- Identification of a license to allow the preservation and protection of concepts within the OS paradigm.
- Development of the concept creation framework.

8.5. Further work

This research has opened many avenues for further research, the potentials of OS and online collaborative product design is immense. Listed are some areas which might be considered for further research:

⇒ Social relations have a great impact in the way people contribute in OS environments. It would be interesting to see what causes this and could this be used an incentive to motivate users in to contribution (see Gilbert and Karahalios, 2009).

⇒ Many peripherals have been designed for virtual environments; it would be interesting to see how one may incorporate them in the concept creation process to provide the users with a more immersive experience during creation.

⇒ Visual impact via simulations is powerful, therefore the use of only simulations such as Poser to present the project scenario, project discussions and possible solutions.

⇒ OPD^3 medical initiative could be considered as a bridge between the medical sector and academia. Key stage 3 to postgraduate students could be invited and encouraged to part-take in projects as part of their coursework or even thesis.

⇒ SL (Second Life) is a virtual environment in which users can perform activities, integrating SL with OPD^3 to provide a complete virtual experience in concept creation could be a possibility.

8.6. Conclusion

The aim of the project was to develop an open source virtual design framework for medical device development. It is acknowledged that the research has addressed this with a viable solution. It is believed as a result of this research the medical sector can adopt a culture of innovation through OS. Allowing geographically dispersed individuals to contribute in the concept creation of cheaper medical applications to the global market that have the potential to save lives.

Listed below are the objectives that were set for the research followed by conclusions:

a. Identify technicalities associated with the development of the open source virtual online web-based collaborative framework. Comparative analysis and review of the OS literature provided the basics knowledge that was required to understand the technical aspects of the subject. A further study on virtual collaborative design provided an insight in to common methods and technologies adopted to allow product creation.

b. Design the virtual environment to ensure it should encompass the required concept creation activities to accommodate the development of medical applications. A generic concept creation model for medical applications was designed in chapter 4. This was further enhanced by identifying the required activities for each of the stages in chapter 6. The generic model was a result of literature review and analysis of different models. The model was enhanced by stating

c. Investigation in to IPR protection and OS licences and proposing the most pertinent ways to protect the ownership of concepts. The protection of ideas is a very important topic. Research in to IPR and its connectedness with OS was identified. Common OS licenses were identified and the most appropriate selected for the site. Terms and conditions were developed as an agreement between the site administrators and the participants.

d. Perform a live user trial by inviting specialist people to part-take in the initiation and the developmental stages of the project. A live user trial was performed based on the framework developed and implement in the second objective. UML use case and activity diagrams were considered to identify the system requirements and activities. The script was used as a guideline in the implementation of the framework. Once the site was fully implemented users were asked to participate in the creation of a project. Students, doctors, teachers and design engineers were amongst the participants. Once a core team had been

developed and the project specification clarified, the design team was able to produce high quality feasible concepts.

e. Design User documentation *(good practise guide)* is which can be followed by participants to successfully follow through the virtual environment. A good practise guide was developed to allow users to successfully navigate through the concept creation arena. Graphical illustrations were provided with descriptions of all the necessary stages of the process. A PDF version was uploaded on to the site; users were able to use this as a referencing point for all their queries

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Appendix A: Terms and Conditions

Terms and conditions

Please read the OPD3 Medical initiatives terms and conditions prior to participating in any of the hosted projects.

Introduction

By entering in to this covenant, you are requesting to part-take in the medical initiative at www.opensource-cranfield.org. If you are registering on behalf of your company it is advised that you contact the administrator prior to proceedings at: r.alam@cranfiled.ac.uk or r.roy@cranfield.ac.uk. The OPD3 team may regularly revise the terms and condition which you must either accept or reject. In case of rejection your membership will be terminated and all access to listed/unlisted projects will be ceased.

Participation

Upon approval by the administrative team you will be able to view project proposals, how ever you must comply by the demands of the project initiator to part-take the project(s). The project initiators reserve the right to reject or withdraw the application at discretion at any time which will result in the suspension of services assigned to the project.

You must register on to the site by www.opensource-cranfield.ac.uk; multiple accounts created by a single user will result in immediate suspension and a six month ban. You a re responsible for keeping you user name and password secure should you in any condition loose or forget you detail you may seek to retrieve them by completing the forgotten password form.

Intellectual Property

As a registered user all the contents uploaded on to the OPD3 server including designs, CAD models and any other forms of contributions will transfer all the IP to the project initiator. You must grant the right to utilise all the contents for project development purposes. By confirming and uploading a design you guarantee that you are the sole creator of the content and that your contribution does not infringe and commercial IP.

OPD3 is based on the creative commons license; each project hosted will specify which of the CC licenses have been assigned. As an agreement you must fully comply and adhere to the respective license. Additionally by submitting your ideas and physically contents you herby give OPD3 and its hosted project teams the permission to use the contents to physically produce products.

Contents

Any form of content uploaded on to the server must be initially authorised by the project initiator who will thoroughly assess the legislative aspects of the contents. By uploading contents you are giving the OPD3 team to publicly display your contents without fee to project participants

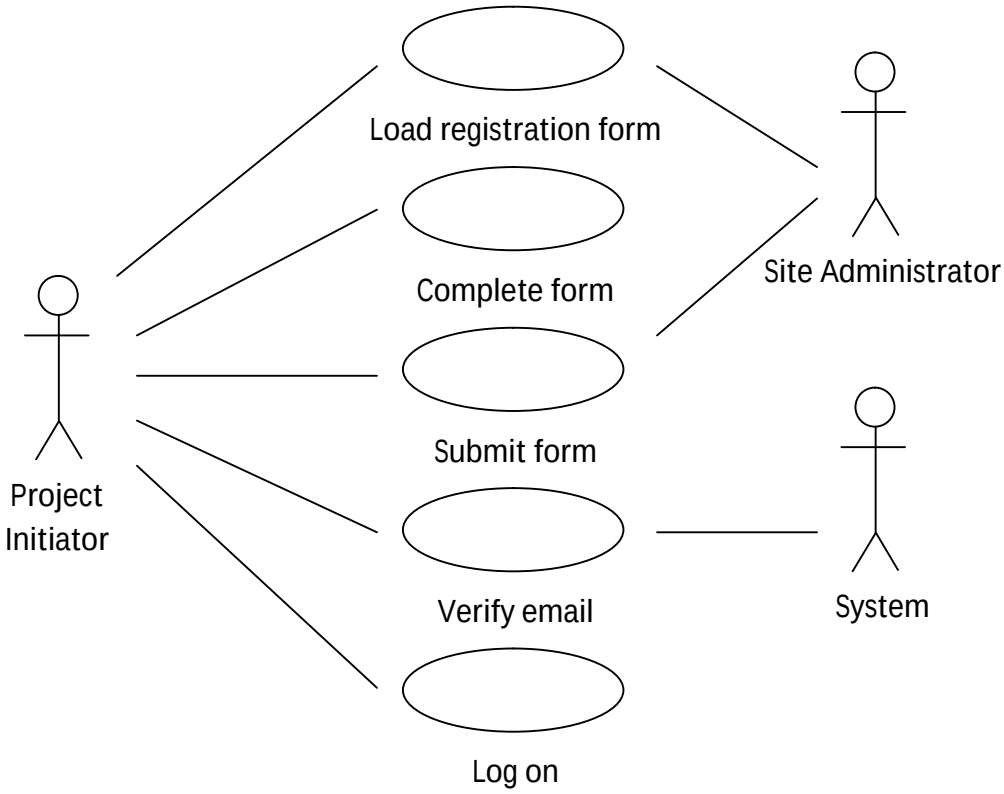
OPD3 will not be held responsible for the loss, theft, damage, intellectual property infringementation of any of the contents. You are advised to verify all contents prior to submission, should there be an investigation in to accounts of such crimes you will be held responsible for all actions committed.

Termination

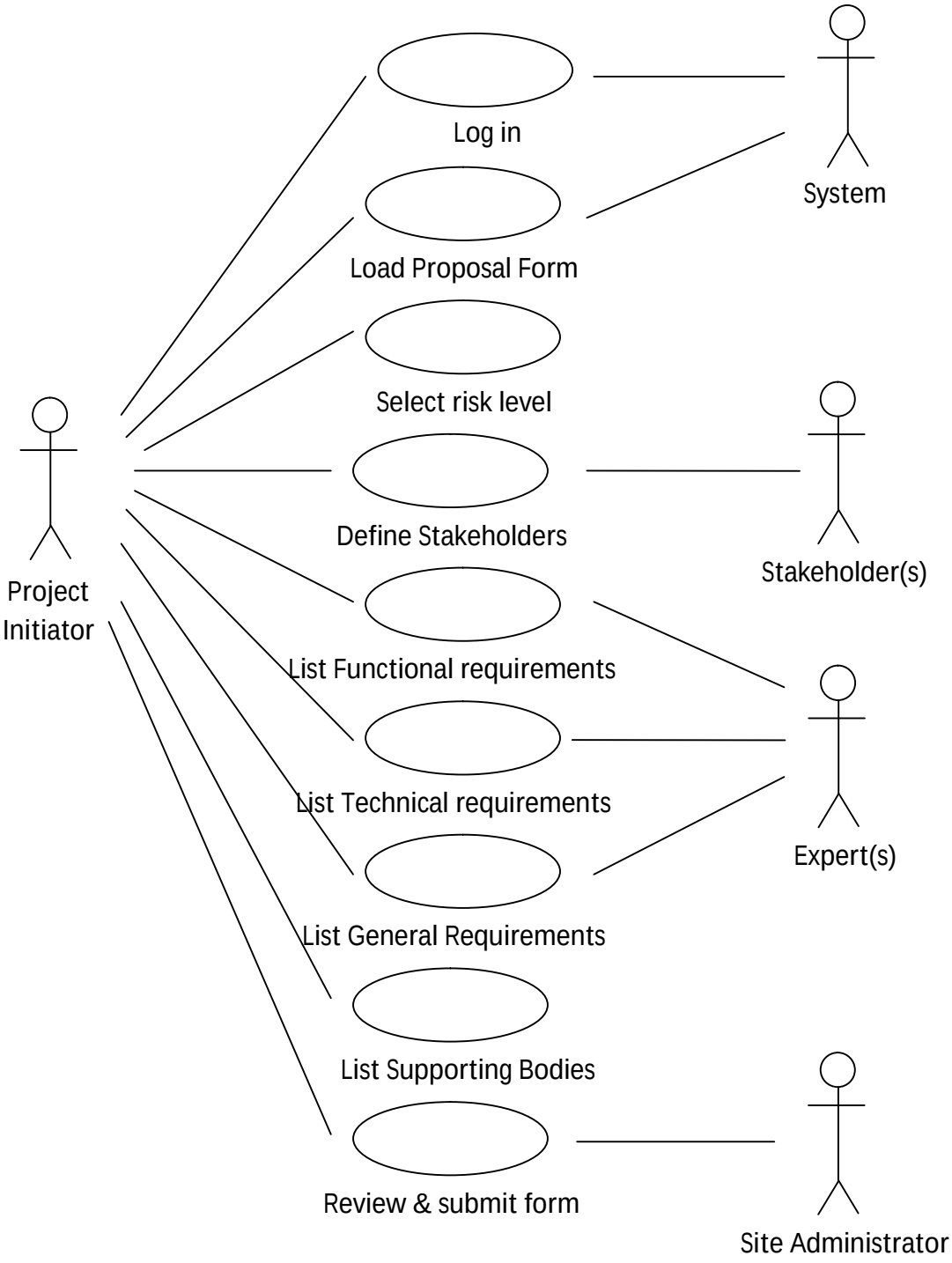
By providing a written notice to the website administrator with a justifiable explanation will terminate this agreement. You must contact the project initiator requesting the removal of your contents, specifying comments, designs, CAD files etc. It can take up to 60 days before all the specified contents are removed from the public domain.

Appendix B: Use Case Diagrams

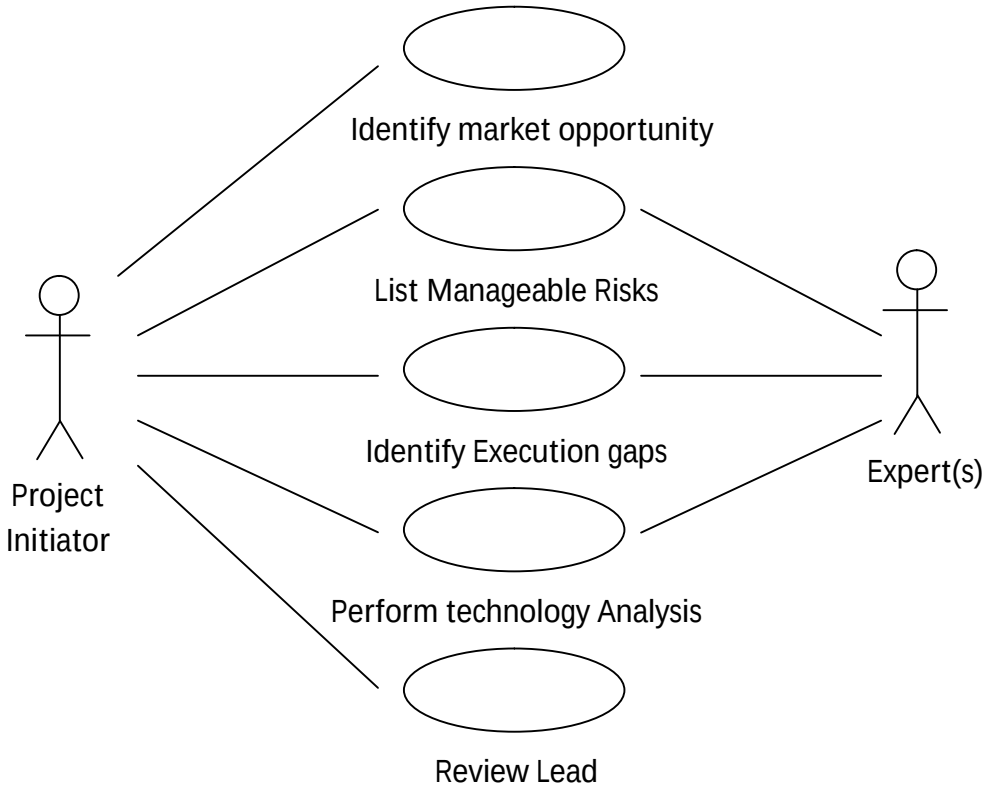
Registration



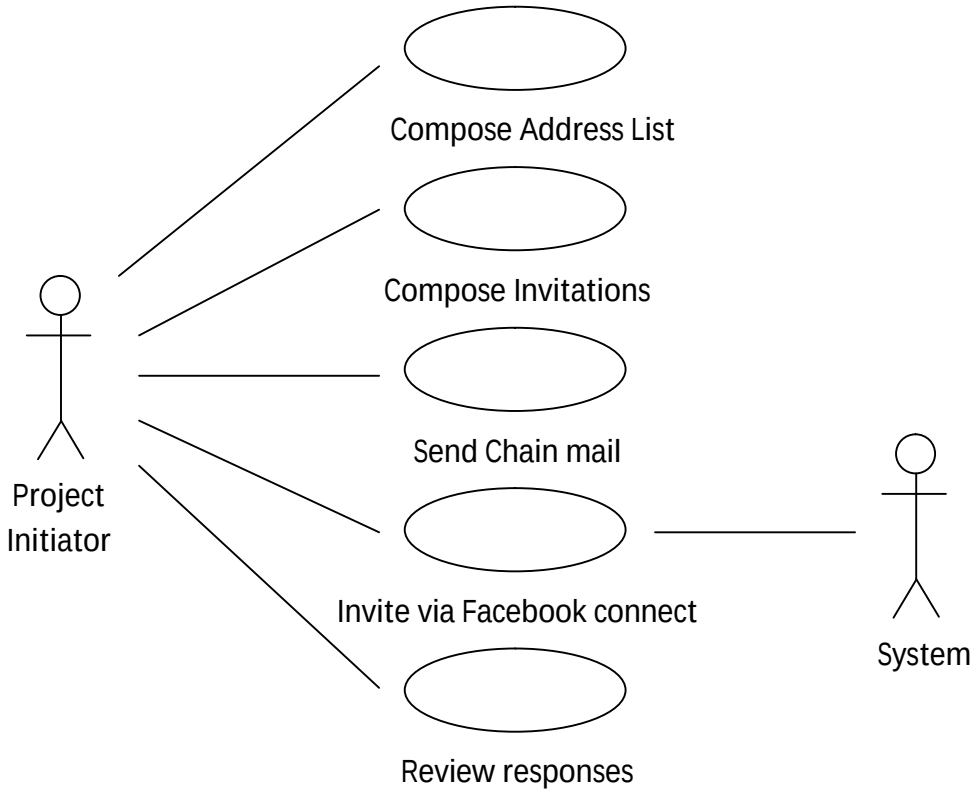
Project Proposal



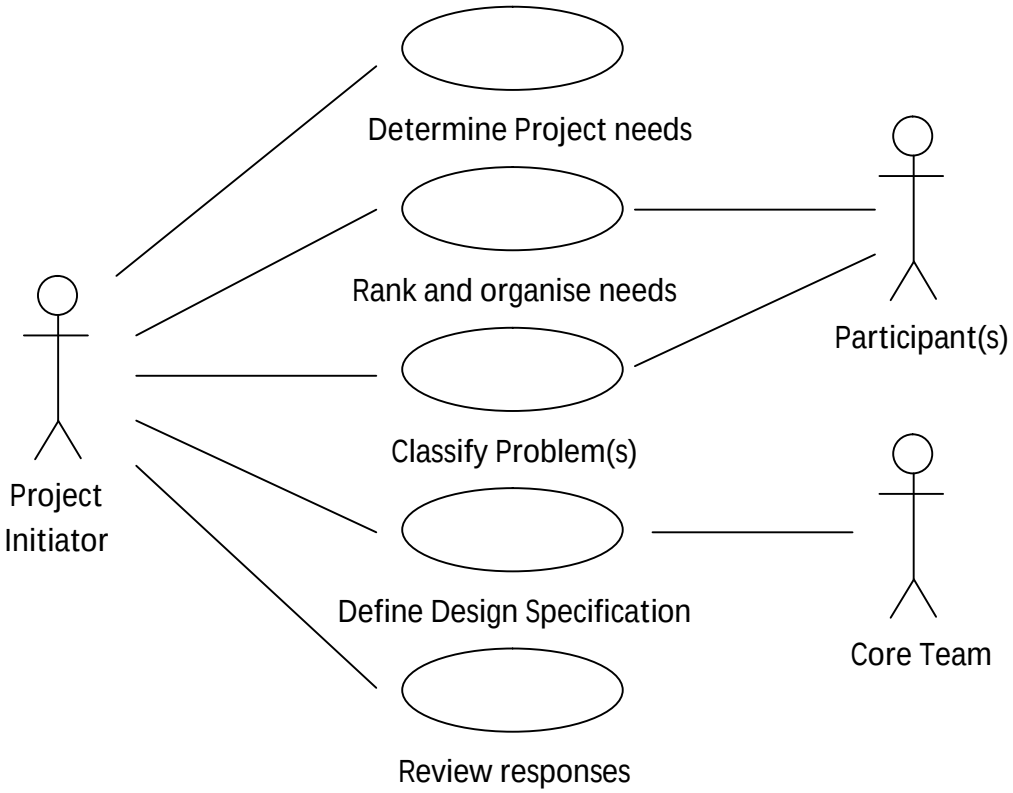
Establish Technical Specification



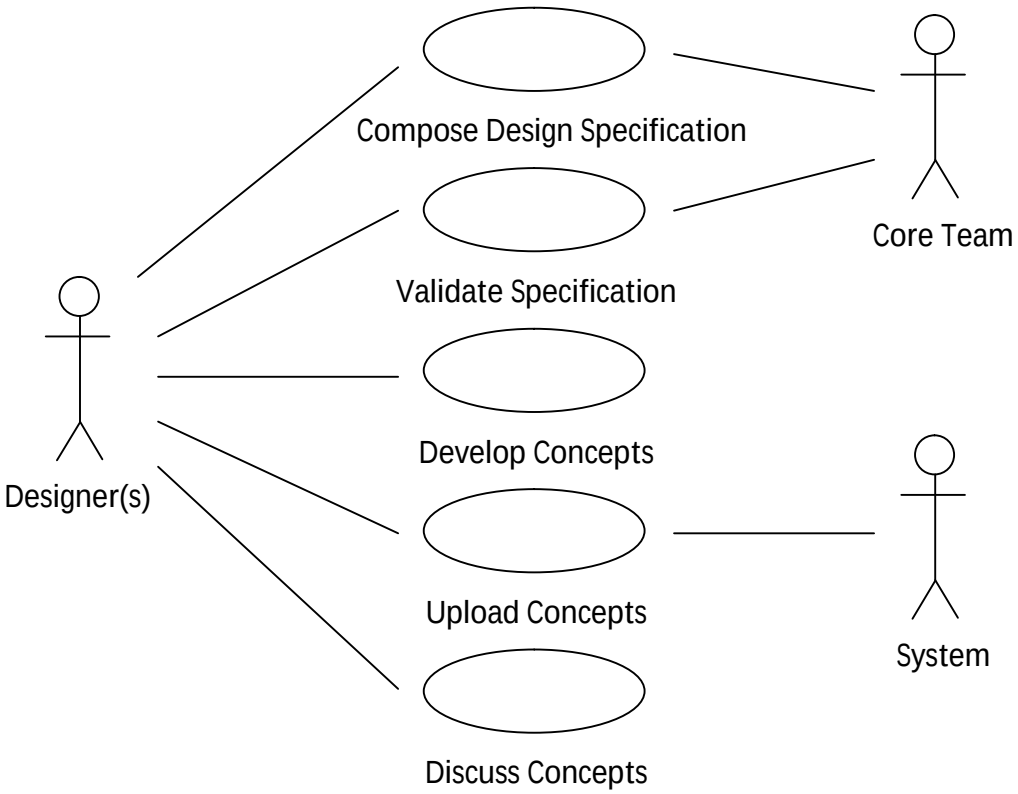
Invite Participants



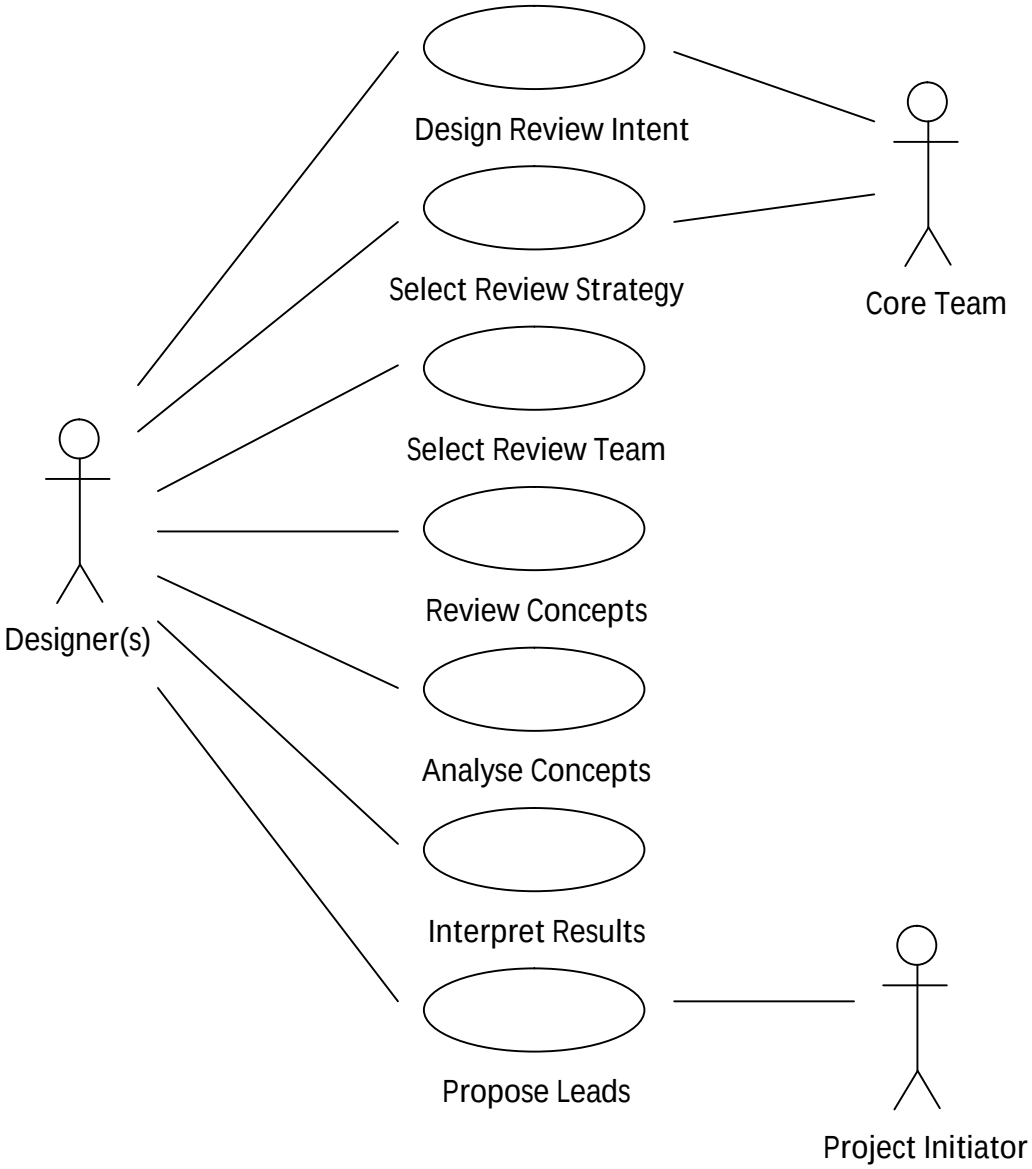
Project Ideation



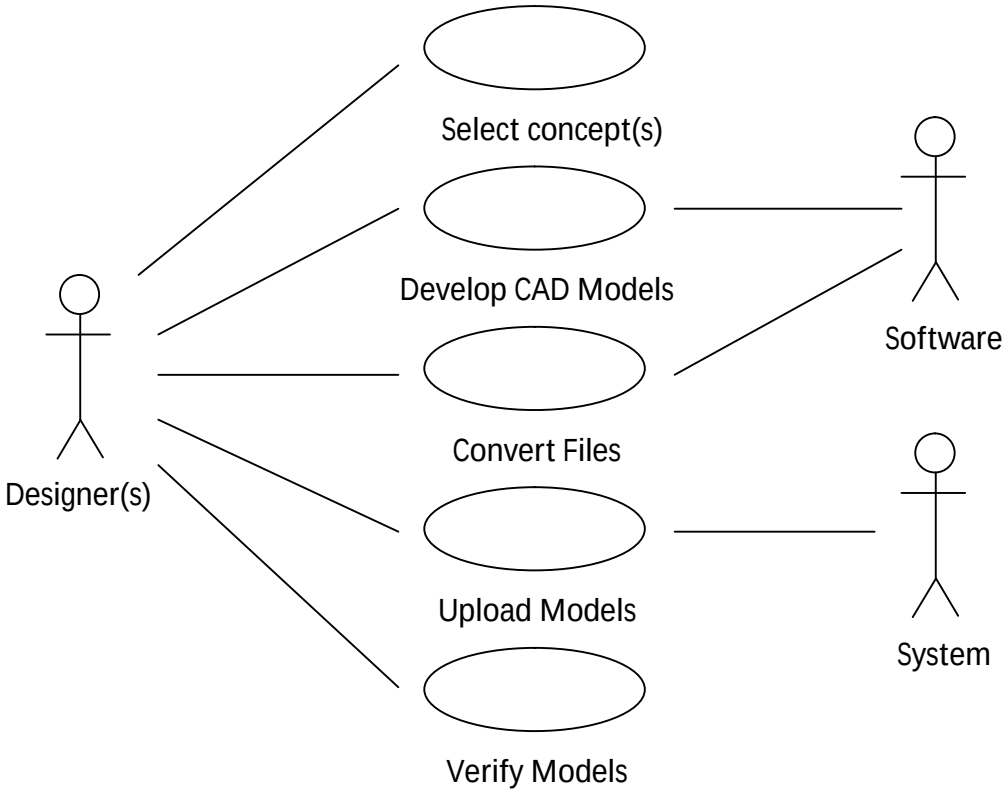
Generating Concepts



Review Concepts



Develop CAD Models



Appendix C: Good Practice Guide

Medical Initiative

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Introduction

'Concept creation made easy'

The user guide coincides with the website and aims to provide users with sufficient explanations. The purpose of the user guide is twofold; (1) familiarisation with the general navigations and (2) understanding the concept creation process, tools and. Screenshots and explanations have been provided to provide the reader with adequate resources for understanding.

Prior to registration users are advised and encouraged to read and understand the licensing (Creative Commons) and terms and conditions. By registering on the site or on to any project you are automatically registered under the creative commons attributes license.

Any one identified to abuse the site in any way will find their privileges suppressed and in critical cases accounts may also be terminated. All comments and contributions made by that user will also be destroyed, it is therefore important one remains within the limitations assigned by the authorisers.

Should you encounter any difficulty in understanding any part of the user guide you may put forth your questions to the design team at: r.alam@cranfield.ac.uk

General Navigation

A screenshot has been provided of the page; relevant modules have been highlighted and given a numerical value which are then used as a baseline for discussion.

Homepage

The homepage is the welcoming and introductory page to the site, it contains three modules which have been highlighted and numbered in figure 0.1. One may use this page to register on to the site, gain an understanding of the OPD^3 mission and visualise existing projects that are currently held on the site.

Figure 0-1: Three modules highlighted from the OPD^3 Homepage

Module 1: Registration

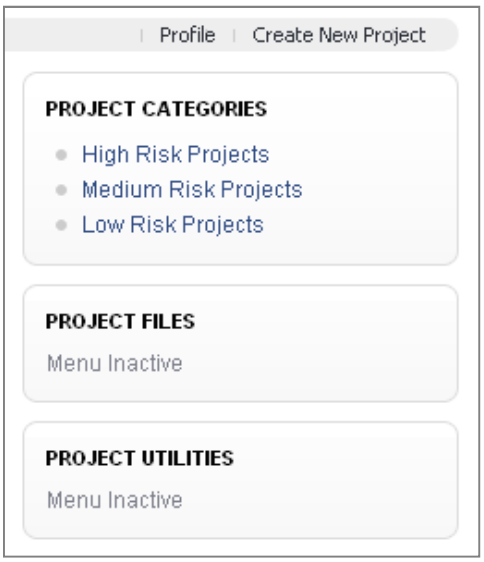
In order to participate and gain full access to the site and its features registration is required. Anonymous visitors may view projects and the limited contents without registration. The registration process is very simple, after completing the registration form one will receive a validation email which upon confirming will allow them to become a recognised member of the site.

Figure 0-2: Registration module

Module 2: Medical Initiative Banner

The banner is an interactive flash based portal which displays relevant information regarding the OPD^3 Medical Initiative. It covers the introduction, definition, process, benefits and details of the initiators.

The intent of the banner is to graphically provide sufficient amount of information to the viewer to gain a basic understanding on what the initiative is about.



Module 3: Project Toolbox

The tool box is used to view ones profile make modifications accordingly. It is also used to generate new projects, which will be covered in the next section.

Medical applications are organised in to three distinctive categorise. By selecting any of the categories one is exposed to the projects currently being held in that portal.

The project files and utilities portal is inactive until one signs in to the site. These restrictions ensure privacy and security is maintained.

Figure 0-3: Project toolbox

Additional Functions

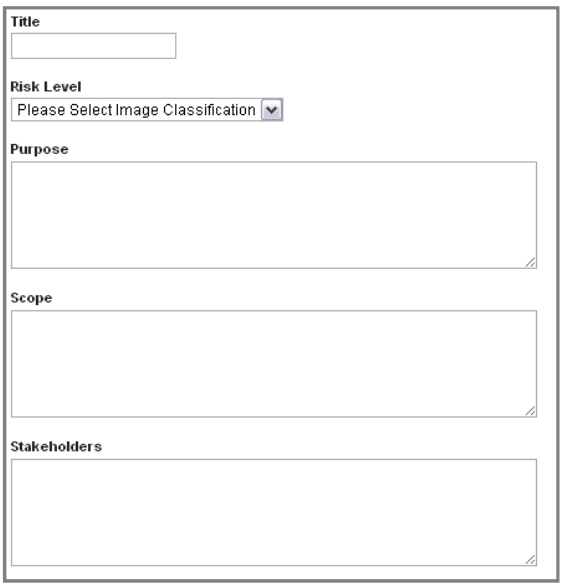
The template has been designed with some standardised functions, these include the following:

1. The *Search* function allows one to search the entire site from a given word or phrase. The search provides a thorough examination of all the articles and comments hosted on the site, providing the user with maximum results.
2. By clicking the *Contact Us* tab, a contact list is presented.
3. OPD^3 is a virtual collaborative environment; by selecting the *Community* tab the user can access either the forum or the web-log feature.
    a. The forum is used to discuss a number of topics either general or subject specific to projects. This promotes in the expansion of the networks and allows exhaustive discussions to take place.
    b. Web-logs are used to provide details of changes and developmental discussion of projects.

Project Creation & Modification

Creating a new project

By selecting *create new project* tab as seen on figure 3 the user will be required to complete and submit a form. Figure 4 displays the opening section of the form.



Some of the most prominent fields are: Title, project risk levels, purpose, stakeholders etc.

All ten fields are mandatory and must be completed; failing to complete all the fields will result in a message being displayed to the user.

The sole purpose of the form is to allow the project initiator to record technical and non-technical aspects and requirements of the project.

Figure 0-4: Creating a new project form

Upon completion and submission of the form, a request will automatically be sent to the administrator. Project(s) will not be made active and publically visible until the administrator verifies the contents and feasibility of the project proposal.

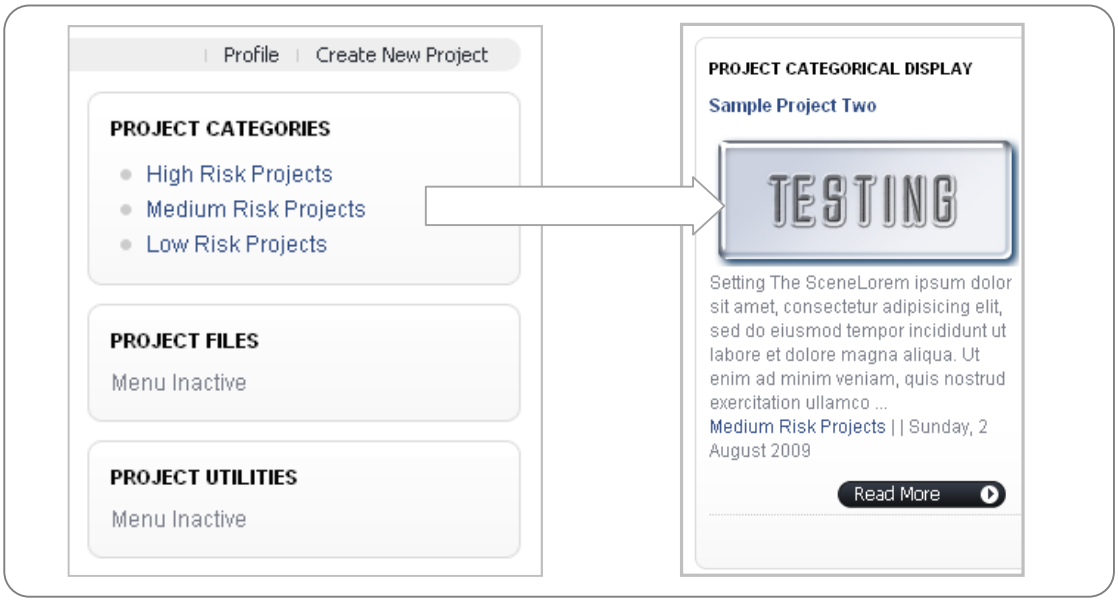


Figure 0-5: Project display screen

After assigning a category in the project proposal, the initiator can visualise the summary of the project, as seen in figure 5. The *project display* disseminates a summary of the project, its author, the date of publish and a project image. By selecting *Read More* a detailed project list is generated.

Project Development

After entering the *detailed list,* the user is exposed to the virtual arena which holds all the information of that particular project. Four key aspects of the portal have been highlighted in figure 6 followed by a description.

Figure 0-6: Project Details

Four key aspects of the page

1. The project title and the date of publish displayed in bold
2. Additional buttons which allow the user to generate a PDF file of the 'project proposal' email and printing functions are also provided.
3. Details of the project are presented; project image, summary (setting the scene), project requirements and additional information related to the project. Information displayed in this section is automatically extracted and organised form the project proposal form.
4. The project files and utilities is now appearing active which allows the user to enter the virtual arena.

Virtual Arena

The production of concepts in the OPD^3 virtual arena is based on the following key stages:

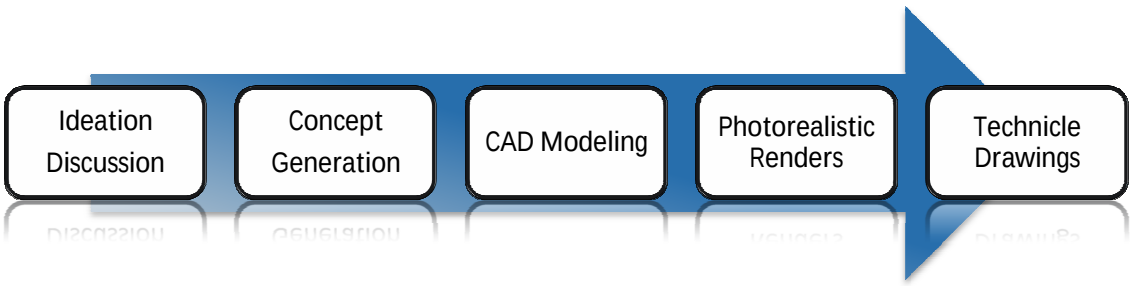


Figure 0-7: Virtual Arena Elements

Ideation/Discussion

The virtual arena initiates with the discussion portal which is intended to be used by all the participants to discuss the project proposal. Registered users can use this tool to come forth with ideas and share it with one another.

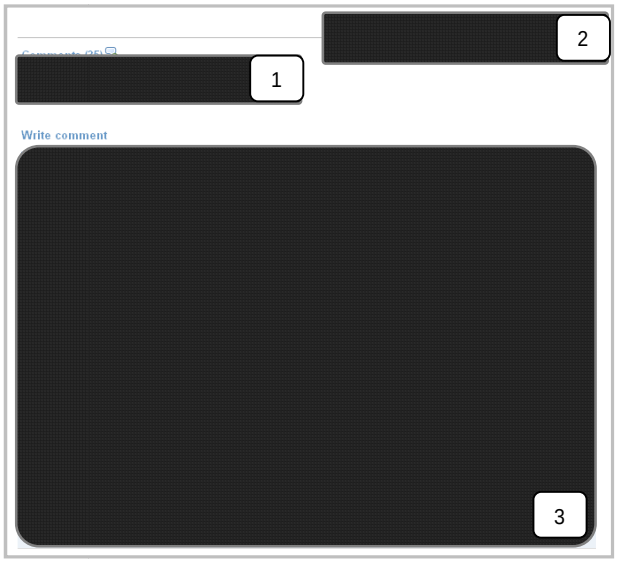


Figure 0-8: Ideation/Discussion section

Three key aspects of the page

1. All comments made by users are recorded and can be viewed by selecting the link which will expand the selection.
2. In order to make a contribution users are required to complete the form; other than text, images and hyperlinks to videos/blogs etc can be uploaded.
   One may sign up to RSS feeds for a regular update by simply clicking the RSS button
3. Features such as bookmark, viewing hits and forwarding email is also provided.

Entering the Virtual Arena

The arena is dissevered in to two modules; the first provides visual representations of the contents and the second serves as an uploading portal, as seen in figure 9.

Figure 0-9: Arena Modules

Arena Module: 1

The arena allows participants to visualise concepts, renders and 2D drawings using a flash image viewer. CAD models are viewed using Cortona VRML viewer and Adobe PDF, details are provided in the sections to come.

Prior to uploading any type of content to the server, users must download the relevant templates and complete them. The templates can be downloaded from the download section, examples have been provided at the end of this document.

Arena Module: 2

In order to process the images successfully one must use the project utilities module to upload images and CAD files. The system accepts JPEG, Bitmap, PNG, GIF and TIFF images. The CAD portal accepts VRML and U3D files which it will display using the universal browser plug-ins. Users must complete a template and zip alongside the original CAD file to make it publicly available.

The CAD template is slightly more detailed than the concept, renders and 2D template. Users must provide details of the software and version used as well as other information which might be of use to a fellow participant.

The project utility also contains an extra tool that can be used for collaborative drawing and sketching. This online flash based tool provides all the necessary tools to develop graphical concepts which can then be viewed by the project team; this has been discussed below in detail.

Uploading Files

In the upload portal the user is able to upload images and CAD files; the process for both has been discussed below.

Uploading Image

To upload a file an image one must click the link top enter the upload portal, via the image upload portal. One can browse for a file, give it a title, description and select the corresponding section for upload (concepts, renders, 2D drawings).

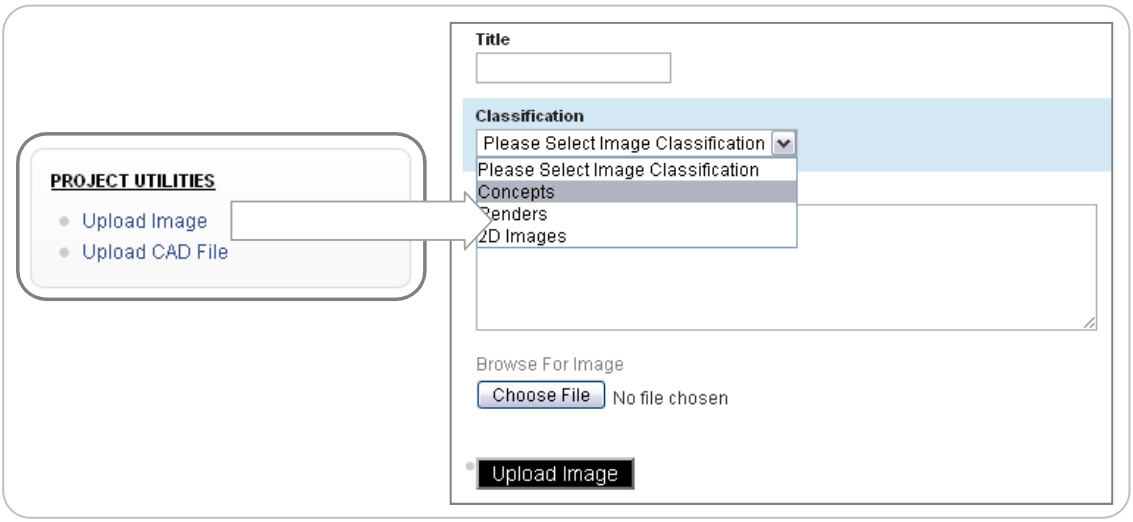


Figure 0-10: Uploading images

Uploading CAD file

A similar procedure is used to upload CAD files, by selecting *Upload CAD File* a form is displayed which one must complete to successfully upload the CAD files.

The user is required to give the upload a title, list the version and provide a description.

A VRML, U3D (PDF) and the original CAD file (compressed, including the template) must be uploaded.

Figure 0-11: CAD upload

Visualising Files

Concepts: users are expected to upload rough sketches, which have been done by hand and then scanned. They may also want to upload digital concepts which have been created

Renders: after creating the CAD models, photorealistic/vector renders can be uploaded in to this portal.

Technical Drawings: 2D Technical drawings, once produced can be uploaded in this section, though all must comply with the BS 8888 standard.

CAD Models: CAD models are to be uploaded in this section; VRML, U3D and the original file must all be uploaded.

Flash viewer: A flash viewer has been used to display the concepts, render and 2D images. One may navigate through all the projects via control over the mouse. By right clicking and selecting full screen will allow one to view the images fully. The concept description can be viewed by clicking the flip icon which is located on the right hand of each concept (as seen in figure 12). By doing so will allow one to view the title and description of the concept but also allow one to download the file. Figure 13 depicts the flash viewer in the renders and 2D images portal.

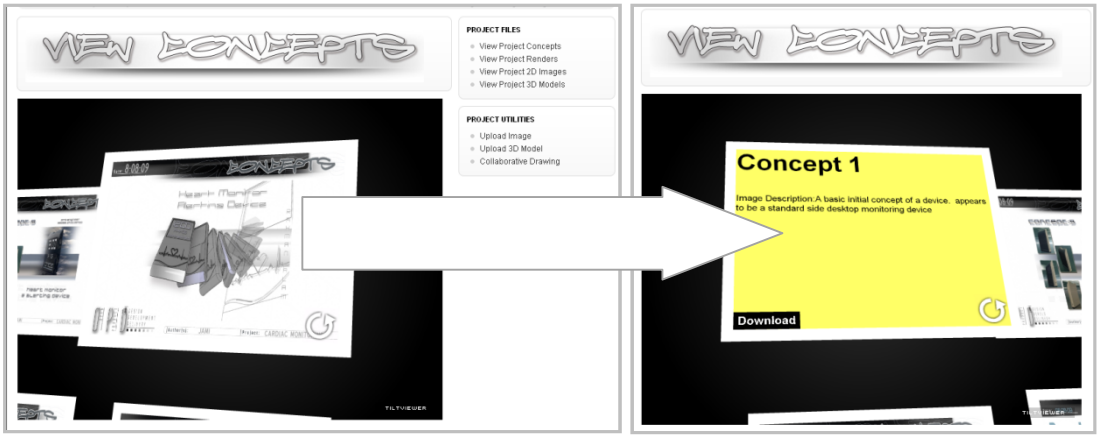


Figure 0-12: Concept viewer

Figure 0-13: Flash viewer showing renders and 2D images

CAD Model Management System

The number of iterations and modifications made to CAD files is very high in number, the regularity of updates, assemblies and patching can differ according to model increases in each project. Only by managing uploads successfully will ensure all discrepancies are eliminated.

The CAD arena is displayed in a tabular format which provides details of the CAD file, which include the version and description. By clicking the *VRML file* the VRML file will open within the browser (subject to plug-in installation). A PDF CAD file can be viewed by clicking the PDF link, figure 14 shows an example of both a VRML and U3D file opened in their respected programs/extensions.

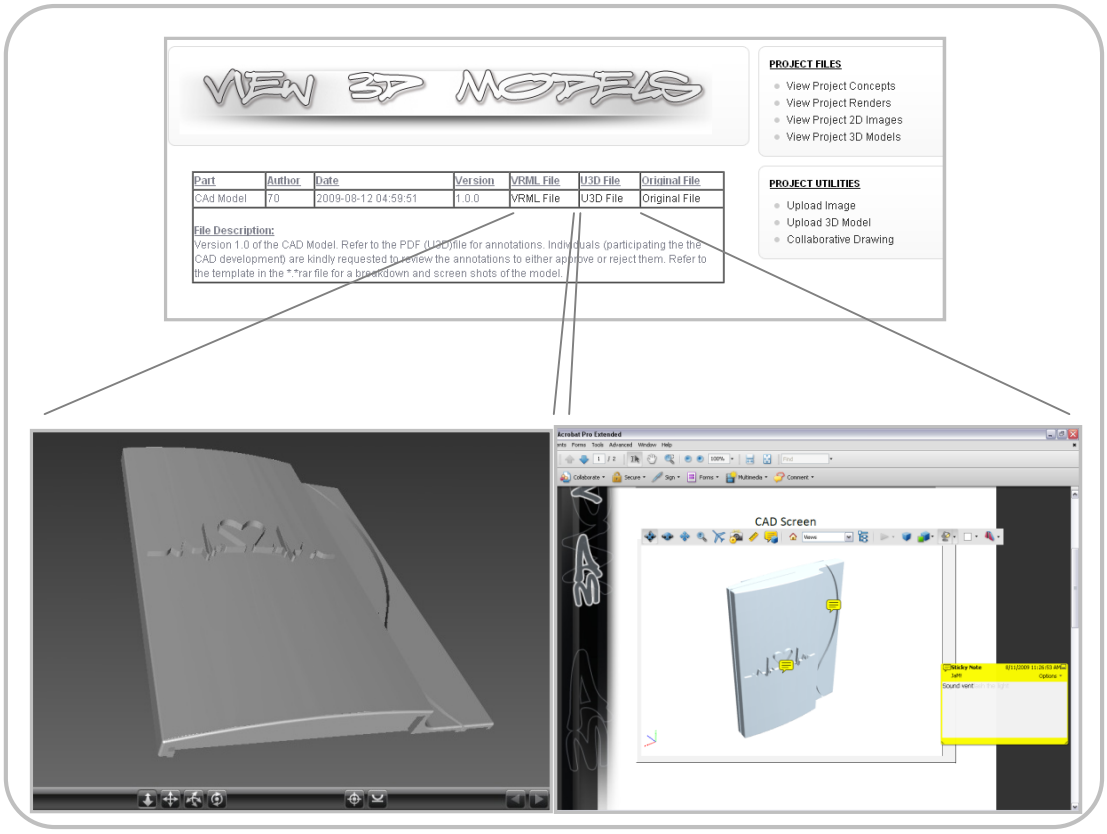


Figure 0-14: CAD viewer showing an example of a VRML and U3D file

By selecting the original file link will begin the download of a compressed file which should includes the following files:

1. Original CAD File
2. CAD Template; detailed description of the CAD file in PDF/Doc format.
3. Read Me file; giving additional information about the contents

Collaborative Drawing

By selecting the *collaborative drawing* in the project utilities menu will direct you towards the drawing arena (figure 15). Two key areas of the menu have been identified and discussed below.

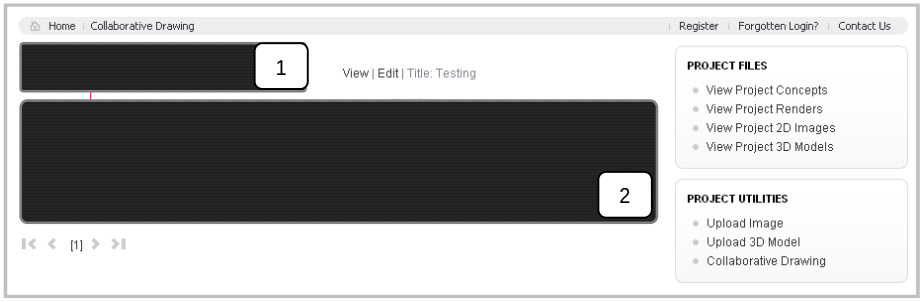


Figure 0-15: Collaborative drawing main page

Two key aspects of the page

1. The menu allows users to view and edit existing images which are available in the preview box, which intact promotes the concept of collaborative drawing. Users are also able to create a new image via this menu by selecting 'new drawing.'
2. The preview box displays miniature previews of existing sketches that have been produced for visual purposes.

Once a new sketch has been selected, the flash based design tool is displayed (as seen in figure 16). Sufficient tools are available for graphics creation and manipulation. Once the user is satisfied with the drawing session they may save it which will be made available in the preview and can be retrieved for further modifications.

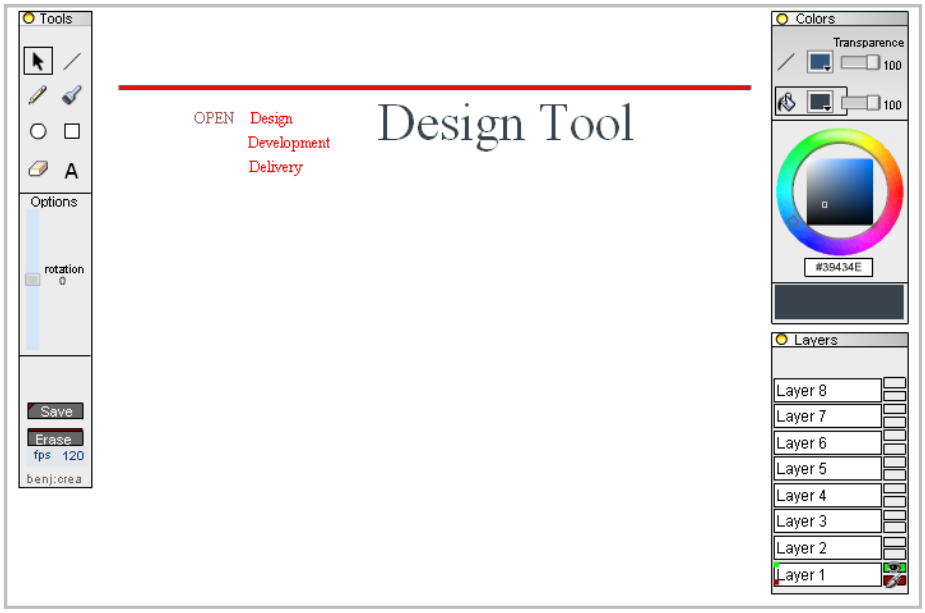


Figure 0-16: Flash based design tool

Requesting Authorisation

OPD^3 have developed a function which allows unregistered members to put forth a request with an attachment (which might be concepts/journal papers etc) for others to see in the project. However one must follow a formal process of completing the request form, upon completion and selection of *send request* an email will be sent to the project authoriser. It's within the rightful authority of the project initiator (administrator) to either accept or reject the contributions.

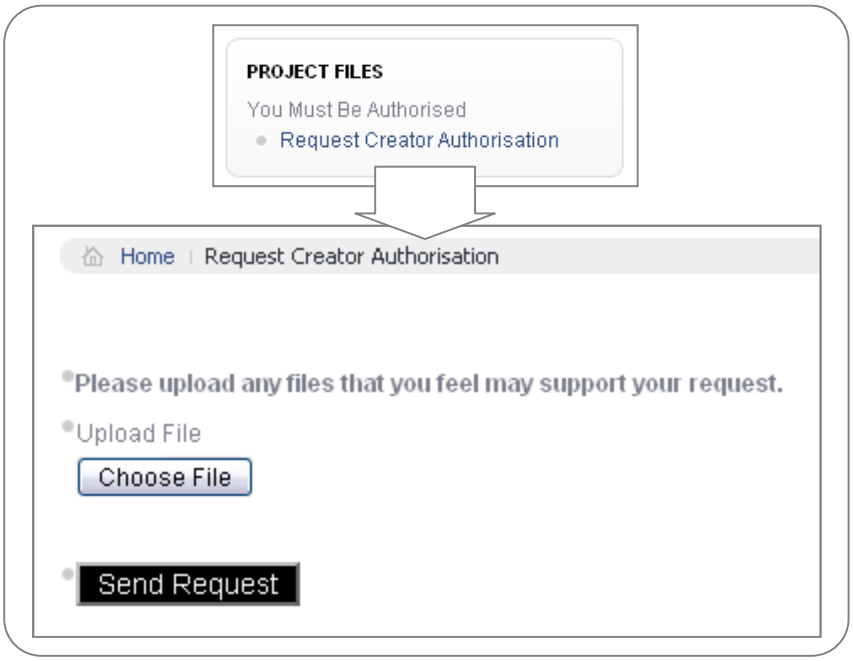


Figure 0-17: Authorisation Request Form

This enhancement feature has been developed to ensure uptight privacy and security is maintained at all times. By opening the gateways to the projects allows the outside audience gives opportunity for exploration. If it is in the interest in the visitor to make useful contributions which may benefit the project community one may use this method by requesting authorisation.

By using the collaborative design tool, one can generate concepts which can be uploaded to the project server; however an unregistered user will need to follow this step for approval.

Downloads

OPD^3 aims to provide all its users with an enriching experience during the concept creation process, the download section contains complimentary programs/extensions which one must consider.

The download section is split in to three sections which include: *applications, templates and viewers.*

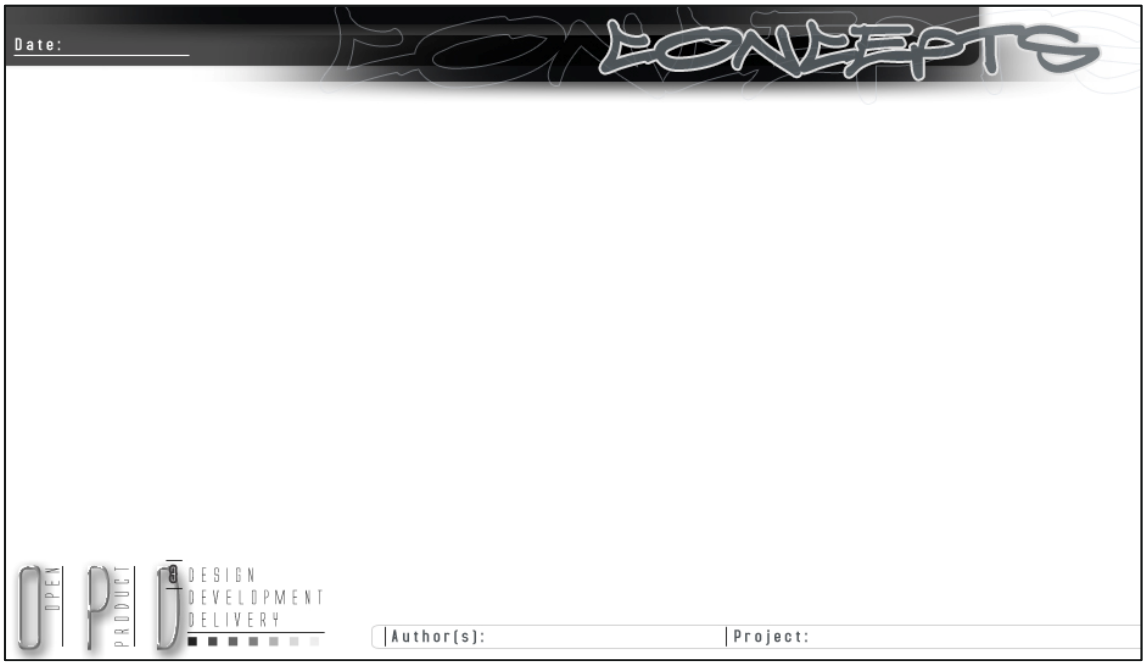
The applications section includes top rated and highly recommended open source graphics applications and CAD packages have been provided.

In order to maximise the experience a number of external extensions must be pre-installed which include: Flash, Adobe Acrobat Reader and Cortona VRML viewer.

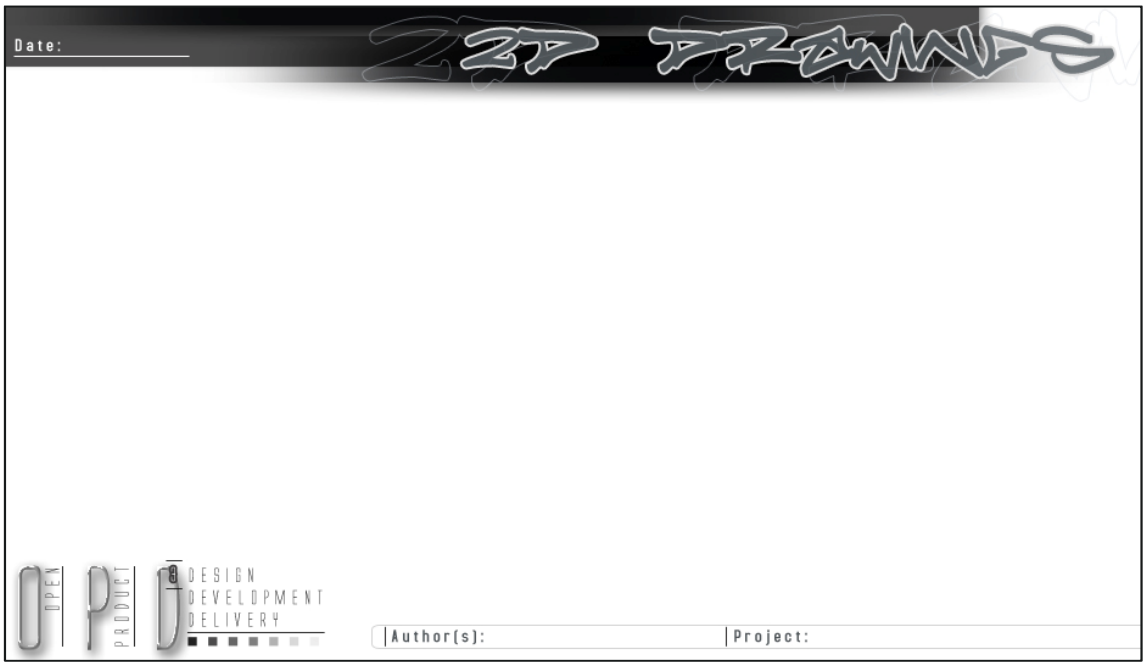
Templates can be downloaded from the download page, in PDF and JPEG format which must be used during the concept creation process.

Templates

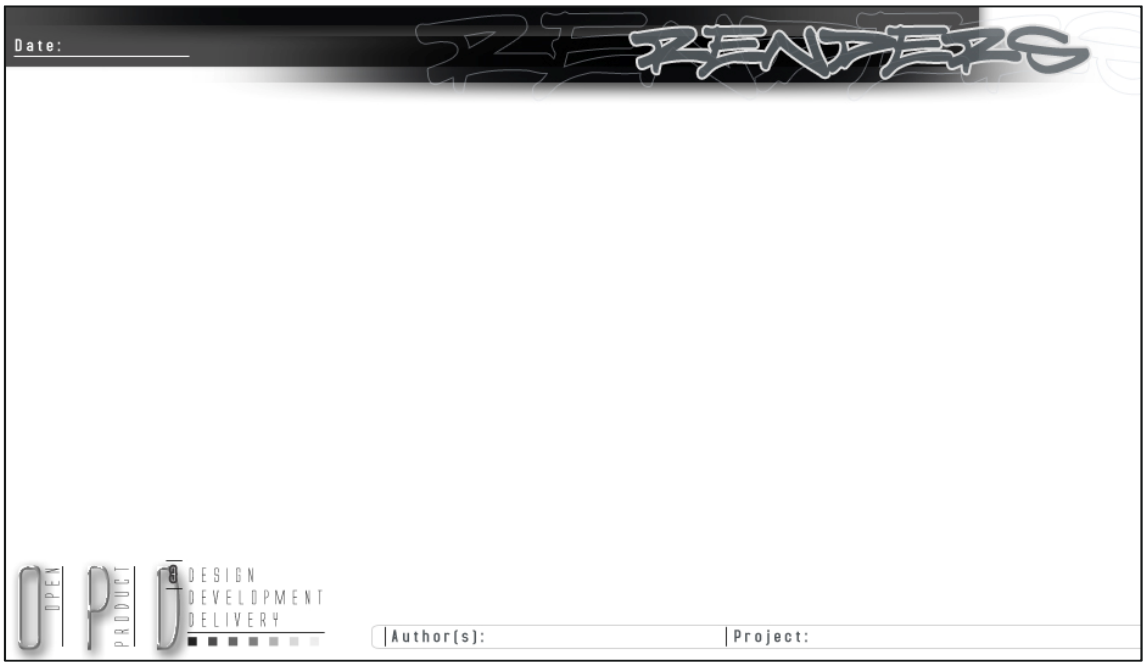
Concept Creation:



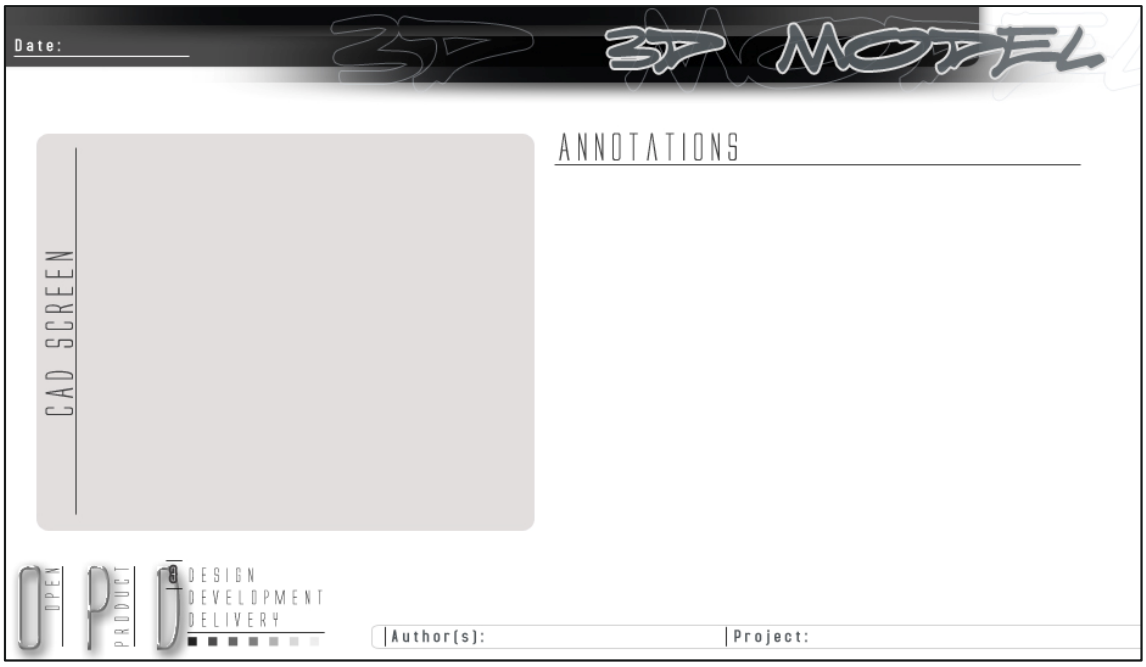
2D Drawings:



Renders:



CAD Model:



MODEL VERSION MANAGEMENT CONTROL TEMPLATE

Date:

Project:

Author(s):

Model Details	Software package used:		
	Software Version:		
	Part/Assembly:	*Part*	*Assembly*
	Number of Parts:		
	Exported formats:	*VRML*	*U3D*
	Compress:	*Yes*	*No*
	Animation	*Yes*	*No*
	Exploded View	*Yes*	*No*
	Rendered	*Yes*	*No*
	Part Function		
	Part Description:		

Screenshots:

Front view
Additional View

Appendix D: User experience Questionnaire Template and Example of Transcript

OPD^3 User Experience Questionnaire

The Design Team is a major part of the OPD^3 Medical initiative, which is in place to ensure all necessary tools/techniques are provided to bring forth an enriching design experience to its users. The objective of this questionnaire is to capture, collate and consider all your comments. By completing this questionnaire would allow the design team to gain a better understanding of user responsiveness through we will be able to put forth ways that could improve the quality of the site.

About You

It is not compulsory to answer all the questions in this section, though the more information you provide would allow the design team to develop an accurate projection of its users.

OPD^3 User Name:	Age:
Background:	Years of experience:
Areas of contribution:	Project Participation:

Part One

Site Awareness/Participation

1) How did you find out about the OPD^3 Medical initiative?

☐ Search Engine ☐ Recommendation ☐ Facebook ☐ Other

2) Did you register as a valid user?

☐ Yes ☐ No

3) Did you initiate a project/ request participation/ received invitation?

☐ Initiated projects ☐ Requested participation ☐ Received invitation

4) Upon registration did you invite others to the project, *if so by what methods?*

☐ Yes ☐ No

Methods:

☐ Facebook invite ☐ Email ☐ Word of mouth ☐ Other

PART TWO

STRUCTURE OF DESIGN ARENA

5) Were you able to navigate through out the *Design Arena* without difficulty?

☐ Yes ☐ No

6) What do you think of the structure of the *Design Arena*?

- ☐ Requires a total re-change
- ☐ Poor
- ☐ Good
- ☐ Excellent, doesn't require any alterations

7) Were you able to find the required information *Design Arena*?

- ☐ Yes, I was able to found information I was looking for
- ☐ Yes, but only in some sections
- ☐ Fairly
- ☐ No, the layout is too complicated

8) What do you think of the theme of the *Design Arena*?

- ☐ Very good
- ☐ Good
- ☐ Poor
- ☐ Very poor

PART THREE

IDEATION SECTION

9) Did you participate in the ideation discussion at any stage of the project?

☐ Yes ☐ No

10) How often did you refer to the ideation comments section during the project?

☐ Never ☐ occasionally ☐ Regularly ☐ All the time

11) Can you please list two advantages and disadvantages of the Ideation section?

Advantages:

1	
2	

Disadvantages:

1	
2	

12) Did you find the RSS feeds function useful?

☐ Yes ☐ No *Comment:* _____

13) What changes would you like to see in the Ideation section?

	_____ _____ _____

PART FOUR

CONCEPT CREATION TOOL BOX AND TECHNOLOGIES	
	14) Did you consider using the open-source graphics applications provided in the download section? ☐ Yes ☐ No *Comment:* _____
	15) Did you use any other graphic application(s) other than the ones provided on the site, *if so which ones(s)*? ☐ Yes ☐ No Comment: _____ _____
	16) Did you use the *flashitool* for online sketching and annotation of designs? ☐ Yes ☐ No *Comment:* _____
	17) Did you take advantage of the mind-mapping application during the brainstorming sessions? ☐ Yes ☐ No *Comment:* _____
	18) Did you consider using the templates provided to display concepts, renders and 2D drawings? ☐ Yes ☐ No *Comment:* _____
	19) Do you believe the method used to manage designs is accurate and effective? ☐ Yes ☐ No *Comment:* _____
	20) Were you able to create, save and upload concepts in to the arena without any difficulty? ☐ Yes ☐ No *Comment:* _____
	21) After uploading your design, were the files clearly displayed or did they become distorted? ☐ Highly distorted ☐ Slight distortion ☐ No distortion
	22) Do you believe the interactive flash banner portrays the concepts in an acceptable, elegant and correct manner? ☐ Yes ☐ No *Comments:* _____

23) Would you prefer seeing the concepts, renders and 2d drawings sections separate or all displayed all together on one page in a single flash banner?

☐ Single ☐ Together *Comment:* _____

PART FIVE

CAD DATA COLLABORATION

24) Do you think the layout of the CAD portal is suitable?

☐ Yes ☐ No

25) Which of the viewers listed did you have preinstalled?

☐ Flash ☐ PDF Viewer ☐ Cortona3D

Which of the viewers were you required to download?

☐ Flash ☐ PDF Viewer ☐ Cortona3D

26) Which of the universal file format did you prefer for visualisation of the CAD file and why?

☐ VRML ☐ U3D *Comment:* _____

27) Did you at any point annotate, modify and reload an existing U3D (PDF) CAD file during project development?

☐ Yes ☐ No *Comment:* _____

28) Did you contribute to an original CAD file uploaded by another team member?

_____

_____

29) Did you work with alongside another registered team member to develop CAD models at any stage of the project?

☐ Yes ☐ No *Comment:*

PART SIX

COLLABORATIVE DESIGN

30) Where there sufficient tools and techniques provided to collaborate with fellow designers?

_____

_____

31) During what part of the project did you collaborate most with either an individual or a team?

☐ Initiation ☐ Ideation ☐ Design ☐ Post Design

32) How effective is the collaborative method provided by OPD^3?

☐ Very Effective ☐ Effective ☐ Somewhat ☐ Not effective

33) Were you able to handle conflicts and solve design challenges without difficulty?

☐ yes ☐ No *Comment:* _____

34) At what stage of the project did you utilise resources with a fellow participant of the project?

_____

_____

_____

PART SEVEN

DESIGN CONTRIBUTION & LICENSING	
	35) OPD^3 operates using the open source creative commons license; did you hesitate at any stage in making contributions?
	36) How do you feel about sharing ideas and designs in a team to develop medical products?
	37) Are the terms and conditions clearly listed and easy to follow?
	38) How committed are you in ensuring products are bought to the market? ☐ Very ☐ Some what ☐ Don't Care
	39) Will you continue to participate in new OPD^3 projects and why? ☐ Yes ☐ No *Comments:*
	40) Which additional techniques, tools & technologies can be added to improve the future of the initiative?

The OPD^3 Team would like to thank you for allotting your precious time in the completion of the questionnaire, your comments and feedback will be considered in the development of the site. We aim to work with you to develop a state of the art online collaborative community whose sole purpose is to develop life saving medical applications.

Please email to: r.alam@cranfield.ac.uk

OPD^3 USER EXPERIENCE QUESTIONNAIRE

The Design Team is a major part of the OPD^3 Medical initiative, which is in place to ensure all necessary tools/techniques are provided to bring forth an enriching design experience to its users. The objective of this questionnaire is to capture, collate and consider all your comments. By completing this questionnaire would allow the design team to gain a better understanding of user responsiveness through we will be able to put forth ways that could improve the quality of the site.

ABOUT YOU

It is not compulsory to answer all the questions in this section, though the more information you provide would all the design to develop an accurate projection of its users.

OPD^3 User Name: Steven Jenkins	Age: 35
Background: Graphics designer	Years of experience: 17
Areas of contribution: Conceptualisation	Project Participation: Cardiac MA Device

PART ONE

SITE AWARENESS/PARTICIPATION

41) How did you find out about the OPD^3 Medical initiative?

☐ Search Engine ■ Recommendation ■ Facebook ☐ Other

42) Did you register as a valid user?

■ Yes ☐ No

43) Did you initiate a project/ request participation/ received invitation?

☐ Initiated projects ☐ Requested participation ■ Received invitation

44) Upon registration did you invite others to the project, *if so by what methods?*

■ Yes ☐ No

Methods:

■ Facebook invite ☐ Email ☐ Word of mouth ■ Other

PART TWO

STRUCTURE OF DESIGN ARENA

45) Were you able to navigate through out the *Design Arena* without difficulty?

■ Yes ☐ No

46) What do you think of the structure of the *Design Arena*?

- ☐ Requires a total re-change
- ☐ Poor
- ☐ Good
- ■ Excellent, doesn't require any alterations

47) Were you able to find the required information *Design Arena*?

- ■ Yes, I was able to found information I was looking for
- ☐ Yes, but only in some sections
- ☐ Fairly
- ☐ No, the layout is too complicated

48) What do you think of the theme of the *Design Arena*?

- ■ Very good
- ☐ Good
- ☐ Poor
- ☐ Very poor

PART THREE

IDEATION SECTION

49) Did you participate in the ideation discussion at any stage of the project?

■ Yes ☐ No

50) How often did you refer to the ideation comments section during the project?

☐ Never ■ occasionally ☐ Regularly ☐ All the time

51) Can you please list two advantages and disadvantages of the Ideation section

Advantages:

1	It's a good way to reason with one another
2	One way of sharing ideas in an elaborate way

Disadvantages:

1	The content is as good as the contributions.
2	

52) Did you find the RSS feeds function useful?

■ Yes ☐ No *Comment:*

53) What changes would you like to see in the Ideation section?

	None, its complete as a tool

PART FOUR

CONCEPT CREATION TOOL BOX AND TECHNOLOGIES	54) Did you consider using the open-source graphics applications provided in the download section? ■ Yes ☐ No *Comment: Gimp and Inkscape*
	55) Did you use any other graphic application(s) other than the ones provided on the sire, *if so which ones(s)*? ☐ Yes ■ No Comment:
	56) Did you use the *flashitool* for online sketching and annotation of designs? ■ Yes ☐ No *Comment:*
	57) Did you take advantage of the mind-mapping application during the brainstorming sessions? ■ Yes ☐ No *Comment: it's a good tool*
	58) Did you consider using the templates provided to display concepts, renders and 2D drawings? ■ Yes ☐ No *Comment:*
	59) Do you believe the method used to manage designs is accurate and effective? ■ Yes ☐ No *Comment:*
	60) Were you able to create, save and upload concepts in to the arena without any difficulty? ■ Yes ☐ No *Comment:*
	61) After uploading your design, were the files clearly displayed or did they become distorted? ☐ Highly distorted ☐ Slight distortion ■ No distortion
	62) Do you believe the interactive flash banner portrays the concepts in an acceptable, elegant and correct manner? ■ Yes ☐ No *Comments:*

63) Would you prefer seeing the concepts, renders and 2d drawings sections separate or all displayed all together on one page in a single flash banner?

■ Single ☐ Together *Comment:*

PART FIVE

CAD DATA COLLABORATION

64) Do you think the layout of the CAD portal is suitable?

■ Yes ☐ No

65) Which of the viewers listed did you have preinstalled?

■ Flash ■ PDF Viewer ■ Cortona3D

Which of the viewers were you required to download?

☐ Flash ☐ PDF Viewer ☐ Cortona3D

66) Which of the universal file format did you prefer for visualisation of the CAD file and why?

■ VRML ☐ U3D *Comment: use it regularly*

67) Did you at any point annotate, modify and reload an existing U3D (PDF) CAD file during project development?

☐ Yes ■ No *Comment:*

68) Did you contribute to an original CAD file uploaded by another team member?

No

69) Did you work with along side another registered team member to develop CAD models at any stage of the project?

■ Yes ☐ No *Comment: helping with the drafting features*

COLLABORATIVE DESIGN

70) Where there sufficient tools and techniques provided to collaborate with fellow designers?

yes

71) During what part of the project did you collaborate most with either an individual or a team?

☐ Initiation ☐ Ideation ■ Design ☐ Post Design

72) How effective is the collaborative method provided by OPD^3?

■ Very Effective ☐ Effective ☐ Somewhat ☐ Not effective

73) Were you able to handle conflicts and solve design challenges without difficulty?

■ yes ☐ No *Comment:*

74) At what stage of the project did you utilise resources with a fellow participant of the project?

None

PART SEVEN

DESIGN CONTRIBUTION & LICENSING

75) OPD^3 operates using the open source creative commons license; did you hesitate at any stage in making contributions?

Nope

76) How do you feel about sharing ideas and designs in a team to develop medical products?

I feel it's a good activity and it should be encouraged in schools, colleges and also in work places

77) Are the terms and conditions clearly listed and easy to follow?

Yes

78) How committed are you in ensuring products are bought to the market?

☒ Very ☐ Some what ☐ Don't Care

79) Will you continue to participate in new OPD^3 projects and why?

☒ Yes ☐ No *Comments: I want to see it develop further*

80) Which additional techniques, tools & technologies can be added to improve the future of the initiative?

A detailed description of each section for new comers, or a user guide would be Useful.

The OPD^3 Team would like to thank you for allotting your precious time in the completion of the questionnaire, your comments and feedback will be considered in the development of the site. We aim to work with you to develop a state of the art online collaborative community whose sole purpose is to develop life saving medical applications.